

**The effects of carer-delivered individual Cognitive
Stimulation Therapy for people with dementia
on carer wellbeing**

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Thesis submitted for the degree of Doctor of Philosophy

March 2017

The effects of carer-delivered individual Cognitive Stimulation Therapy
for people with dementia on carer wellbeing

Declaration

I, Boi Phuong Leung, confirm that the work presented in this thesis is my own.

Where information has been derived from other sources, I can confirm that this has been indicated in the thesis.

Date

Boi Phuong Leung

“Do your little bit of good where you are;
It's those little bits of good put together that overwhelm the world.”

Desmond Tutu

Abstract

Background

Cognitive stimulation therapy has been developed to improve cognition and quality of life (QoL) for people with dementia. Little is known of the effects on carer wellbeing when individual cognitive stimulation therapy (iCST) for people with dementia is delivered by family carers.

Aims

- To investigate the effects on carer wellbeing when there is carer involvement in cognition-based interventions (CBIs) for people with dementia
- To assess the effects of carer-delivered iCST for people with dementia on carer wellbeing

Methods

A meta-analysis review was performed. A multicentre, single-blind, randomised controlled trial (RCT) recruited 356 dyads of people with mild to moderate dementia and their carers. Dyads in the intervention group received iCST three times weekly over 25 weeks. A qualitative study recruited a subgroup of 23 dyads of people with dementia and family carers who completed the iCST intervention to take part in semi-structured in-depth interviews.

Results

The meta-analysis review indicates that carer involvement in CBIs may improve carers' QoL with effect size Hedges' $g = 0.22$; 95% CI of 0.02-0.42 and $p \leq 0.03$ and reduce carers' depressive symptoms with effect size Hedges' $g = 0.17$; 95% CI of 0.02-0.32, and $p \leq 0.03$. The findings of the RCT show that there are no benefits of carer-delivered iCST on carers' mental/physical health, mood and relationship quality with their relative. Carers however reported an improvement in their health-

related QoL (HR-QoL) EQ5-D with a mean difference of 0.06, 95% CI 0.01-0.10, $p \leq 0.01$ and less depressive symptoms when they completed more sessions. The qualitative results show that participating in iCST may be a useful tool that provides people with dementia and their family carers with opportunities to enjoy mentally stimulating activities, stay active and bring them 'closer' encouraging them to communicate with each other.

Conclusion

Carer involvement in CBI for people with dementia may improve carers' QoL and reduce their depressive symptoms when they complete more sessions with their relative. The findings have important implications for service delivery to family carers and people with dementia.

Acknowledgements

Firstly, I would like to express my sincere gratitude to my primary supervisor Professor Martin Orrell for giving me the opportunity to undertake my PhD. Without his tremendous support, invaluable advice and encouragement, my achievement would not have been possible. My heartfelt thanks go to him for guiding me in the right path and paving the way for my development as a researcher.

I am immensely grateful to my secondary supervisor Dr Vasiliki Orgeta for her constant support and encouragement throughout my PhD. My sincere thanks go to her for giving me invaluable comments and sound advice. Her guidance has greatly contributed towards my understanding of dementia research.

My deep appreciation goes out to the iCST team; Dr Lauren Yates, Fara Hamidi, James Sinclair and all staff and researchers across the various sites. Their excellent work during data collection was an invaluable contribution towards my PhD. My special thanks to the family carers and people with dementia who gave their time to help with the research. I would like also to thank Dr Michaela Poppe, Dr Emese Csipke, Dr Lauren Yates, Dr Amy Streeter and Dr Alex Feast for their advice and support.

Lastly but not least, my very special thanks go to my late mother for her unconditional love and encouragement. Although she could not wait to see my achievement, I know she always believed in me. Words can't express how grateful I am to my husband Stephen and my children Vivien and Simon for their love, patience and tireless support which served as a secure anchor during the hard and easy times.

An overview of my PhD

The present thesis describes the work conducted during my PhD research evaluating the effects of carer-delivered iCST for people with dementia on carer wellbeing. This work is a standalone piece of research that was nested in the iCST randomised controlled trial (RCT).

The iCST trial was funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) programme, project number 08/116/06. The contractual start date was July 2010.

Aims and objectives of the iCST RCT trial

To evaluate the clinical and cost-effectiveness of carer-delivered individual cognitive stimulation therapy (iCST) for people with dementia and their family carers compared with the treatment as usual (TAU) group.

The objectives of the iCST RCT trial

- To develop an individual, home-based intervention of CST for people with dementia and their family carers
- To assess the effectiveness of iCST in improving cognition and quality of life for people with dementia, and mental and physical health in carers in comparison to TAU
- To assess the cost-effectiveness of iCST in comparison to TAU

Main outcome measures

1. People with dementia

- Primary outcomes included cognition and quality of life

- Secondary outcomes included behavioural and psychological symptoms, activities of daily living, depressive symptoms and relationship quality with their relative (carer)
2. Family carers
- Primary outcome was mental/physical health (Short Form Questionnaire-12 items)
 - Secondary outcomes included carer health-related quality of life (European Quality of Life-5 Dimensions), mood symptoms and relationship quality with their relative (the person with dementia)
3. Costs were estimated from health and social care and societal perspectives

The methodology described in this PhD has also been reported in full in the Health Technology Assessment (HTA) report below:

Orgeta, V., Leung, P., Yates, L., Kang, S., Hoare, Z., Henderson, C., Whitaker, C., Burns, A., Knapp, M., Leroi, I., Moniz-Cook, E. D., Pearson, S., Simpson, S., Spector, A., Roberts, S., Russell, I.T., de Waal, H., Woods, R.T., Orrell, M. (2015). Individual Cognitive Stimulation Therapy for dementia (iCST): effectiveness and cost-effectiveness pragmatic multicentre randomised trial. *Health Technology Assessment*, 19(64) 1-108. doi: 10.3310/hta19640.

My PhD research and contribution to the iCST trial

I developed my PhD proposal during my employment as a research assistant (RA) on the iCST trial. I was therefore not involved in the initial design of the trial including the selection of outcome measures. However, prior to starting my PhD research, I was given opportunities to participate in preliminary discussions of the methods of the trial (e.g. outcome measures, sample size, data analysis, treatment integrity and mixed methods) and discussed these with my PhD primary supervisor Professor Martin Orrell (the trial chief investigator), my secondary supervisor, Dr Vasiliki Orgeta (the trial co-ordinator) and other principal investigators.

With the guidance and support of my supervisors, I developed my PhD research proposal, formulated the hypotheses, design and conducted the data analysis in the current PhD evaluation. For example, the use of a mixed method was initially proposed in the iCST protocol, but the methods were not described in detail, and there were no suggestions in terms of theories that supported the investigation of the effects of carer-delivered iCST for people with dementia on carer wellbeing. For the purposes of my PhD research, I developed a theoretical framework of carer-involvement in cognition-based interventions, conducted a systematic review of the literature, designed intervention adherence materials (specifically carer diaries, adherence questionnaires for carers and researchers), contributed to the iCST RCT designed and conducted a qualitative study which was embedded in the RCT.

As the PhD student and the RA for the iCST trial, I was responsible for recruitment, data collection, data analysis, the development of the iCST intervention and trial data management (e.g. data collections from other sites, imputing data). For example, during the iCST development phase I was part of the research team that developed the intervention materials and took a leading role in organising the iCST consensus conference, conducting the online survey and organising carer training and designing the iCST activity workbook. Beside this, I was responsible for the qualitative analysis of data collected during the development phase of the trial. I assisted the iCST trial coordinator to setup sites outside London and was responsible for monitoring visits and providing telephone support to participants in the treatment group. I also supported unblind researchers in all other sites through monthly telephone support.

I carried out the qualitative study to explore the experiences and perspectives of people with dementia and their family carers who took part in the iCST intervention.

This qualitative study was part of my PhD for which I recruited a total of 23 dyads of people with dementia and their family carers who took part in the iCST intervention. Prior to data collection, I identified the distinctive features of qualitative data collection methods and developed the qualitative interview topic guide.

I conducted the data analyses of carers' adherence to the intervention by using IBM SPSS version 22 software. Paired t-tests were used to compare carers' knowledge of the iCST intervention, confidence in delivering iCST and carers' engagement with the person with dementia at the set-up and monitoring visits. I also analysed the data in relation to carers' support needs and their satisfaction with the support they received from the unblind researchers over the course of the intervention (25 weeks).

Furthermore, I attended monthly teleconferences with the North Wales Organisation for Randomised Trials in Health (NWORTH) Clinical Trials Unit and with health economists based at the London School of Economics (LSE) to update them about current recruitment, data collection and discuss other relevant issues related to the trial. This experience offered me the opportunity to enhance my knowledge in running RCTs and obtain good analytical and research skills. I also contributed to the writing and submission of the final report to the funding body (Health and Technology Assessment, HTA).

This PhD thesis comprises of 6 chapters.

Chapter 1 provides background in dementia, interventions for dementia, an overview of dementia caregiving, and research in carers of people with dementia and psychosocial interventions developed to support them.

Chapter 2 describes the process of developing a theoretical framework of carer involvement in cognition-based interventions (CBIs) for people with dementia. This process includes 1) Identifying theories, 2) Understanding the Stress Process Model (SPM) of dementia caregiving and 3) Identifying a model of carer involvement in CBIs for people with dementia: Theoretical perspectives.

Chapter 3 presents a systematic review and meta-analysis of carer involvement in CBIs for people with dementia on carer wellbeing. This chapter includes the aim of the systematic review, search methods, inclusion and exclusion criteria, identification of studies, quality assessment of included studies, data analyses, results and interpretation of findings including implications.

Chapter 4 presents the iCST trial reporting specifically on carer outcomes which was part of my PhD research that was nested into the trial. The Medical Research Council framework was used to develop and evaluate the iCST intervention. This work includes 1) the use of a theoretical framework, 2) developing an understanding of the intervention and its possible effects, 3) gathering evidence to support the theoretically hypothesised intervention effects 4) evaluating effects of the intervention via a RCT and 5) conducting a qualitative study that was embedded in the RCT to explore the experiences of people with dementia and their carers taking part in the intervention.

Chapter 5 presents results of the effects of carer-delivered iCST for people with dementia on carer wellbeing and the qualitative findings of participants' experiences of taking part in iCST.

Chapter 6 discusses the findings of the quantitative and qualitative results (iCST trial carer outcomes and qualitative study) and how these are related to the theoretical framework I developed alongside results of my systematic review. This chapter also considers implications of my findings for future research in cognitive stimulation interventions for people with dementia. Finally, I bring together all the findings to present an integrated conclusion.

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Publications

1. **Leung, P.**, Orgeta, V., & Orrell, M. (2017). The effects on carer wellbeing of carer involvement in cognition-based interventions for people with dementia: a systematic review and meta-analysis. *International Journal of Geriatric Psychiatry*.doi:10.1002/gps.4654.....
2. **Leung, P.**, Yates, L., Orgeta, V., Hamidi, F., & Orrell, M. (2017). The experiences of people with dementia and their carers participating in individual cognitive stimulation therapy. *International Journal of Geriatric Psychiatry*.DOI:10.1002/gps.4648
3. Orrell, M, Yates, L., **Leung, P.**, Kang, S, Hoare, Z., Whitaker4, C., Burns, A., Knapp, M., Leroi, I., Moniz-Cook, E., Pearson, S., Simpson, S., Spector, A., Roberts, S., Russell, I., de Waal, H., Woods, R., Orgeta, V. (2017). The impact of individual Cognitive Stimulation Therapy (iCST) on cognition, quality of life, caregiver health, and family relationships in dementia: A randomised controlled trial. *PLoS Med* 14(3): e1002269.....
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Ethical approval and trial registration

Ethical approval was obtained through the East London 3 Research Ethics Committee (ref no.10/H0701/71) in January 2010. The project was registered as a clinical trial (ISRCTN 65945963) in May 2010, and granted approval in September 2010 (see Appendix 1).

The trial was registered with the North East London Foundation Trust (NELFT) Research and Development (R&D) department, University College London (UCL), Barnet, Enfield and Haringey Mental Health NHS Trust (Participant Identification Centre [PIC]), Bangor University, Betsi Cadwaladr University Health Board, Humber NHS Foundation Trust, the University of Manchester, Manchester Mental Health and Social Care Trust, Lancashire Care NHS Foundation Trust, Dorset Health Care University NHS Foundation Trust, Lincolnshire Partnership NHS Foundation Trust, Norfolk and Suffolk NHS Foundation Trust, Devon Partnership NHS Trust and Northern Devon Healthcare NHS Trust.

Abbreviations

ACHEIs	Anticholinesterase inhibitors
AD	Alzheimer's disease
ADAS-Cog	Alzheimer's Disease Assessment Scale – Cognitive
BSI	Brief Symptom Inventory
BSI-A	Brief Symptom Inventory-Anxiety
BSI-D	Brief Symptom Inventory-Depression
CAPE-BRS	Clifton Assessment Procedures for Elderly – Behaviour Rating Scale
CBI	Carer Burden Inventory
CBIs	Cognition-based Interventions
CDR	Clinical Dementia Rating Scale
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CR	Cognitive Rehabilitation
CS	Cognitive Stimulation
CT	Cognitive Training
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition
EQ-5D	EuroQol measure of health-related quality of life
FU1	First follow-up
FU2	Second follow-up
GHQ -12	General Health Questionnaire
HADS-A	Hospital Anxiety and Depression Scale-Anxiety
HADS-D	Hospital Anxiety and Depression Scale-Depression
iCST	individual Cognitive Stimulation Therapy
MADRS	Depression Montgomery-Asberg Depression Scale
MBPC	Memory and Behaviour Problems Checklist
MDRS	Mattis Dementia Rating Scale
MMSE	Mini Mental State Examination
MNSS	Marital Needs Satisfaction Scale
NICE	National Institute for Health and Care Excellence
NINCDS-ADRDA	National Institute of Neurological and Communicative Disorders and Stroke- Alzheimer's Disease and Related Disorders Association
NWORTH	North Wales Organisation for Randomised Trials in Health
PGCM	Philadelphia Geriatric Center Morale Scale

QCPR	Quality of Caregiver/Patient Relationship
QoL	Quality of life
RCT	randomised controlled trial
RSS	Relative's Stress Scale
SCIE	Social Care Institute for Excellence
SD	Standard deviation
SE	Standard error
SF-12	Short Form Health Survey-12 items
SF-36	Short Form Health Survey-36 items
SMD	Standardised mean difference
SSQ	Social Support Questionnaire
TAU	Treatment as usual
VaD	Vascular dementia
VAS	Visual analogue scale
WHOQOL-BREF	World Health Organisation Quality of Life Assessment Short Version

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PL	Phuong Leung (researcher, UCL)
VO	Dr Vasiliki Orgeta (trial co-ordinator, UCL)

1 Chapter 1 Introduction

1.1 Ageing and the epidemiology of dementia

Rising life expectancy is contributing to a rapid increase in the number of older adults in the UK. It is estimated that over 11.6 million (17.8% of the population) aged 65 and over and 1.5 million (2.3% of the population) aged 85 and over live currently in the UK. Since 2005, the UK population aged 65 and over has increased by 21% and the population aged 85 and over has increased by 31%. The number of males aged 85 and over has increased by 54% since 2005, compared to a 21% increase for females (Mid-2015 Population Estimates UK Office for National Statistics, 2016). As the ageing population increases, the number of older people with dementia is also expected to rise (Sosa-Ortiz, Acosta-Castillo, & Prince, 2012). Although several risk factors have been identified that contribute to risk of developing dementia such as genetic effects, age, gender, ethnicity, physical health, life style (e.g. smoking and alcohol consumption), obesity, education (less years in education early in life), comorbidity and environmental factors (Chen, Lin, & Chen, 2009), advancing age remains the single most important risk factor for developing dementia (Luengo-Fernandez, Leal & Gray 2010).

Many epidemiological studies around the world indicate that Alzheimer's is a disease that crosses ethnic, cultural and geographical boundaries (Jicha & Carr, 2010; Shafqat, 2008). It has been estimated that there were over 47 million people living with dementia worldwide. This number is expected to increase to more than 131 million by 2050 (Prince et al., 2016). In 2014, in the UK alone there were 850,000 people with dementia, of which 773,502 were 65 years or over. By 2025, the number is expected to rise to 1.14 million (Alzheimer's Society, 2014). Dementia costs the UK economy £23 billion per year, which is twice as much as for cancer, three times more costly compared with heart disease and four times more costly than caring for

people with stroke. However, only 2.5% of the government's medical research funding is spent on dementia research while 25% is spent on cancer research (Dementia 2010). Given its increasing prevalence, it is predicted that the cost associated with dementia will rise to £34.8 billion per year in 2026 (McCrone, Dhanasiri, Patel, Knapp, & Lawton-Smith, 2008). These projections have implications for health and social care provision and for the health and wellbeing for people with dementia and their family carers.

1.2 Current thinking in dementia

Dementia is a chronic neurodegenerative brain disease that causes a decline in memory and communication associated with loss of independence, withdrawal from social activities and behaviour disturbances known in the literature as neuropsychiatric symptoms (2015 Alzheimer's disease facts and figures, 2015). Dementia is a leading cause of disability in older people (WHO, Dementia - A Public Health Priority 2012) and for people living with dementia, their carers and families it can be a challenging experience (Sosa-Ortiz, Acosta-Castillo, & Prince, 2012). Carers of people with dementia are the most vulnerable group of carers who often experience high levels of stress, feelings of guilt, depression and other types of psychological distress (Contador, Fernandez-Calvo, Palenzuela, Migueis, & Ramos, 2012; National Collaborating Centre for Mental, 2007).

Currently no treatments are available to cure or prevent progression of the illness (2015 Alzheimer's disease facts and figures, 2015). Pharmacological treatment for AD is very limited and primarily aims at achieving symptom control but not directly addressing the cause of the disease (Eleti, 2016). Non-pharmacological therapies are hence often used as interventions to maintain or improve cognition, individuals' ability to perform daily activities and improve QoL of people with dementia (Bahar-

Fuchs, Clare, & Woods, 2013; Moon & Adams, 2013; Woods, Aguirre, Spector, & Orrell, 2012).

Dementia is one of the greatest challenges for society with an enormous economic impact on the healthcare system, and a significant impact on the lives of people with dementia and their families (Dowrick & Southern, 2014). It is therefore important to have a better understanding of dementia (Eleti, 2016) and the different types of neurodegenerative disease (McKhann et al., 1984), in order to provide the right information to support timely diagnosis, enable people to receive the best possible treatments and planning healthcare for the future (Department of Health 2012). The section below briefly gives an overview of the most common types of dementia by outlining current thinking and understanding of these neurodegenerative diseases.

1.3 Dementia subtypes

Dementia is a term currently used to describe a group of syndromes that result in a decline in memory, reasoning and communication skills, and a gradual loss of skills needed to carry out daily activities (Luengo-Fernandez, Leal & Gray 2010). There are several diseases that cause dementia but there is great overlap between them producing heterogeneity and 'pure syndromes' are rare. Alzheimer's disease (AD) being the most common cause of dementia contributing up to 60–80% of cases worldwide (2015 Alzheimer's disease facts and figures, 2015). AD is an age-related neurodegenerative brain disorder that develops over a period of years (James, Bennett, Boyle, Leurgans, & Schneider, 2012), not considered a normal part of ageing (World Health Organisation and Alzheimer's disease International 2015). Research investigating neurobiological markers of AD has shown that it is characterised by two main pathological hallmarks; accumulation of extracellular amyloid protein deposits in senile plaques and intraneuronal accumulation of

hyperphosphorylated tau protein in neurofibrillary tangles. These abnormal protein accumulations result in severe neuronal and synaptic loss (LaFerla, Green, & Oddo, 2007). Amyloid is a breakdown product derived from a larger precursor protein known as Amyloid Precursor Protein (APP). Amyloid is usually processed and eliminated in the healthy brain, but in AD, abnormal processing leads to formation of an abnormally long form known as β -amyloid which cannot be eliminated and accumulates as insoluble and sticky plaques. In AD neurofibrillary tangles consist primarily of a protein called tau which usually acts to stabilise microtubules in the cytoskeleton. In AD these proteins become abnormally phosphorylated leading to collapse of the cytoskeleton and accumulation as neurofibrillary tangles (Sahrim, Nixon, Carare, & Ieee, 2013).

AD is considered a disease that begins well before symptoms appear or first develop and accelerate during the disease process (Todd, Barr, Roberts, & Passmore, 2013; Wilson et al., 2012). AD can affect individuals in different ways, but for most people symptoms begin by having difficulty remembering new information, conversations, names or events and early symptoms often include apathy and depression, which are amongst the most common neuropsychiatric symptoms experienced by people with dementia. As the disease progresses, the abilities to perform everyday tasks are affected by disorientation, impaired conversation, poor problem solving, and mobility such as walking (2015 Alzheimer's disease facts and figures, 2015).

Vascular dementia (VaD) is also an important contributor to the dementia syndrome accounting for 10% of dementia cases (2015 Alzheimer's disease facts and figures, 2015). VaD is characterised by problems in reasoning, planning, judgment, and memory caused by impaired blood flow to the brain and damage to blood vessels resulting from events such as stroke (Khan, Kalaria, Corbett, & Ballard, 2016). VaD

is very common in older people with dementia, with about 50% of people affected having experienced vascular damage such as infarcts (2015 Alzheimer's disease facts and figures, 2015). VaD may progress overtly producing step-wise decline due to cerebral infarctions which cause localised or diffuse damage to brain tissue (Bayer 2011); or be clinically silent characterised by insidious decline in cognition. Prevention of VaD is closely related to maintaining a healthy blood supply. People with hypertension and diabetes have a higher risk of developing dementia. This risk can be reduced by stopping smoking, maintenance of a healthy weight and regular exercise (Alzheimer's Association 2015) and controlling these risk factors. Cerebrovascular disease and Alzheimer's disease pathology commonly occur together producing a Mixed Dementia and neither rarely appear in a 'pure form'.

Dementia with Lewy Bodies (DLB) is the third most common subtype of the neurodegenerative dementias after VaD and accounts for 4% of dementia cases (Alzheimer's Association 2015). It is characterised by the accumulation of alpha-synuclein protein in the cerebral cortex and the nuclei of the brain stem (Burkhardt et al., 1988). DLB patients frequently have complex visual hallucinations, fluctuating cognitive ability, deficits in attention, alertness and often experience slowness of movement (McKeith et al., 2005). Deficits in neuropsychological testing demonstrated in DLB patients are similar to those seen in patients with Parkinson's disease dementia confirming that both are most likely part of the same spectrum of disorder, varying in symptom onset with the location of the primary pathology. Patients with DLB often present with neuropsychiatric symptoms or only cognitive impairment or motor symptoms which can lead to a misdiagnosis of AD or Parkinson's disease or primary psychotic disorder (Zupancic, Mahajan, & Handa, 2011).

Frontotemporal dementia (FTD) is one of the most common forms of young-onset dementia (Rosness, Engedal, & Chemali, 2016), i.e. onset in symptoms under 65 years (Bang, Spina, & Miller, 2015). FTD is associated with frontotemporal lobar degeneration pathology which is characterised by frontal and anterior temporal lobe atrophy, which often presents clinically with behavioural, executive function and language impairments (Rabinovici & Miller, 2010). FTD is caused by several pathological entities defined by the presence of specific abnormal protein accumulations (Mackenzie 2010). FTD dementia is classified into three subtypes that includes: 1) the behavioural-variant which is associated with early behavioural change (e.g. mood swings, lack of emotion, short term memory deficits, and repetitive movement) and executive impairment, 2) non-fluent variant of primary progressive aphasia which is associated with progressive impairment in speech, grammar, and word output and 3) the semantic variant of primary progressive aphasia which is a progressive disorder of semantic knowledge and naming (Arvanitakis, 2010; Bang et al., 2015).

Despite increasing research to improve understanding of the dementias, the nature of the neurobiological changes that trigger and develop neurodegenerative disease remain largely unknown (Lansdall 2014). Recent reviews of research to date suggest that more work is required to understand the natural history and progression of the dementias, and their pathogenesis in order to comprehend the complexity of dementia-related cognitive decline, the contribution of biomarker and neurobiological changes, and the contribution of genetic and lifestyle factors associated with these changes (Ritchie, Terrera, & Quinn, 2015).

1.4 Interventions for Dementia

1.4.1 Pharmacological treatments for dementia

Dementia is characterised by neurodegenerative changes in the brain that result in progressive cognitive decline. Dementia is a disease that leads to death (National Collaborating Centre for Mental Health 2007). The progression of dementia depends on the underlying pathology, early diagnosis, and the effectiveness of available treatment (Carrion, Aymerich, Baillés, & López-Bermejo, 2013). Current targets of pharmacological research aim to identify treatments to prevent or alleviate the progression of symptoms of dementia (Alzheimer's Association Report, 2015; Buschert, Bokde, & Hampel, 2010). While there are currently no treatments to reverse the course of dementia, certain pharmacological treatments can maintain or slow cognitive decline (Carrion et al., 2013). In some cases, medication may treat cognitive functions or mood, but not everyone will benefit from it (Bates, Boote, & Beverley, 2004). While research still shows an absence of effective treatments for dementia (Cummings, Morstorf, & Zhong, 2014), dementia care is focused on providing appropriate psychosocial support for people with dementia and their families (Samsi & Manthorpe, 2014).

1.4.2 Psychosocial interventions for dementia

The World Alzheimer's report 2011 suggests that early therapeutic interventions are important in improving patient outcomes (Prince et al., 2011). In recent years, several systematic reviews have demonstrated the effectiveness of non-pharmacological interventions for people with dementia (Cooper et al., 2012; Olazarán et al., 2010; Sitzer, Twamley, & Jeste, 2006). Non-pharmacological treatments are any interventions that do not involve drugs but address aspects of social, psychological and behavioural symptoms of dementia (Brodaty & Arasaratnam, 2013). Psychosocial interventions can be simple and feasible

approaches for early stage dementia and may have fewer risks and replace neuroleptic therapy without having adverse effects on behavioural symptoms (Ballard et al., 2009). A broad range of psychosocial interventions have been developed to improve the quality of life of people with dementia and reduce mental and behavioural symptoms such as depression, apathy, wandering, poor sleep patterns, agitation and aggression (Alzheimer's Association 2013; Livingston, Johnston, Katona, Paton, & Lyketsos, 2005; Sitzler, Twamley, & Jeste, 2006).

1.4.3 Cognition-based interventions (CBIs) for people with dementia

In the early stages of dementia, people often experience difficulties in processing new information and forming new memories (Christensen, Kopelman, Stanhope, Lorentz, & Owen, 1998). However, evidence has shown that people with dementia can utilise memory information and improve their cognitive performance if provided cognitive support (Backman, 1996). CBIs have been designed to improve cognition and QoL for people with dementia (Clare et al., 2010; Onder et al., 2005; Quayhagen et al., 2000; Spector et al., 2003) and help them to maintain their cognitive function (Christensen et al., 1998). A literature review on cognitive interventions for people with dementia has identified three different approaches used to enhance cognitive function for people with dementia that include cognitive stimulation (CS), cognitive rehabilitation (CR) and cognitive training (CT) (Clare & Woods, 2004).

1.4.3.1 Cognitive stimulation

CS aims at general enhancement of cognitive and social functioning for people with dementia. It provides a range of mentally stimulating activities and opportunities for discussion for people with dementia which are usually conducted in a group setting (Clare & Woods, 2004; Woods & Aguirre et al., 2012). The development of CS is based on the concept of Reality Orientation (RO) that originated in the late 1950s to

help older inpatients with confusion to enhance their mental stimulation and QoL (Taulbee & Folsom, 1966). RO adopts the techniques of presentation and repetition of information to provide the person with greater understanding of their surroundings. For example, by using various visual aids, a facilitator repeatedly presents basic orientation and environmental information such as the name of the person, where they are, the time of the day, the year or the weather. RO can operate as a continuous "24-hour" classroom providing orientation-related activities to people with memory problems (Brook, Degun, & Mather, 1975). The purpose of these orientation-related activities is to establish a group environment (Citrin & Dixon, 1977) thereby improving the patient's sense of control and self-esteem (Spector, Orrell, Davies, & Woods, 2001). One of the earliest studies found that classroom RO led to improvements in cognitive function for people with dementia (Woods 1979), however, during the 1980s, there was increasing concern regarding the nature and approaches of RO, as it was often perceived as being insensitive to the needs of individuals (Dietch, Hewett, & Jones, 1989). Spector et al. (2001) modified RO by conducting a study to test the feasibility of RO and developed a program of CS therapy (CST). A Cochrane review of RCTs examined the effects of CS on cognition and showed that CS improved cognition in people with dementia. Evidence from a small number of studies suggested that CS may also be associated with improvements in QoL and communication (Woods, Aguirre, Spector, and Orrell 2012).

Currently, more than 70% of people with dementia live in the community (Alzheimer Research UK, 2012), therefore, the provision of psychosocial interventions such as CS is increasingly important. The 2006 NICE - Social Care Institute for Excellence (SCIE) guidelines recommend that people with mild to moderate dementia should

be given the opportunity to participate in a structured group CST intervention (Spector, Woods & Orrell, 2008).

1.4.3.2 Cognitive rehabilitation

CR is an individualised approach that focuses on reducing functional disability for people with dementia and maximising their engagement in everyday activities (Clare et al., 2010). Due to diversity in individual impairments, circumstances and preferences, CR is tailored to individual needs by identifying meaningful goals and developing strategies to address these goals (Clare et al., 2010). The CR approach originates from the traumatic brain injury literature and research in stroke (Carney et al., 1999; Cicerone et al., 2000). Several theories of CR argue that although neurological damage cannot be alleviated, people with dementia can carry out daily activities using external memory aids, through practice and the use of compensation or restorative strategies (Buschert, Bokde, & Hampel, 2010). For example, individuals can learn and practise how to manage finances by modifying the way of handling monthly utility bills. Calendars, computers, paper, and pencil aids are used to help to recognise information, making it easier to learn and remember the content. These strategies help maintain cognitive function and assist the person in learning new information (Bourgeois, 1990; Clare et al., 2000) through building on retained cognitive abilities (Clare et al., 2013; Clare & Woods, 2004; Wilson, 2008). The Cochrane review of Bahar-Fuchs, Clare, and Woods (2013) evaluated the effectiveness of CR and CT in people with mild to moderate Alzheimer's disease and vascular dementia and identified only one RCT of individualised CR. Preliminary findings indicate that CR intervention is effective in improving activities of daily living (ADL) for people with dementia (Clare et al., 2010).

1.4.3.3 Cognitive training

CT aims to maintain or improve cognitive function for people with dementia by using repeated and guided practice via a set of standardised tasks. These tasks target specific areas of cognitive function such as attention, memory, learning, executive function, language, perceptual-motor skills or social skills (Sitzer, Twamley, & Jeste, 2006). CT is based on the assumption that regular or routine practice training will lead to improvements in cognitive domains (Bahar-Fuchs, Clare, & Woods, 2013; Clare & Woods, 2004). CT can drive brain plasticity by engaging the person in stimulating cognitive, sensory and psychomotor activities (Olesen, Westerberg, & Klingberg, 2004). CT can be delivered via group training or individualised training (Mimura & Komatsu, 2007) and usually incorporates compensatory and restorative strategies (Belleville, 2008). CT usually adapts three different techniques known as spaced retrieval, dual cognitive support and procedural memory training to enhance learning ability in people with dementia (Mimura & Komatsu, 2007). A recent Cochrane review that examined the effects of CT interventions for people with dementia showed that there were no significant differences between treatment and control groups on cognition and activities of daily living (Bahar-Fuchs, Clare, & Woods, 2013).

1.5 Dementia Caregiving

1.5.1 Demographics of carers in the United Kingdom (UK)

As the number of people with dementia is increasing, more family carers may have to take up the caring role to meet the care demands. Across the UK there are 670,000 carers looking after a relative with dementia (Alzheimer's Society 2013). Many carers may have to give up employment or reduce their work hours to care for their relative. The loss of income is predicted to reach £690 million annually, a cost added to the overall cost of dementia care (Alzheimer's Society, 2012).

The cost of dementia care causes high financial burden on healthcare services (WHO, Dementia - A Public Health Priority 2012). It has been reported that the government social care fund paid out £9 billion (40%) and the healthcare fund £1.2 billion (5%) for the cost of dementia care and the rest of £12.4 billion (55%) is contributed by unpaid carers (Luengo-Fernandez, Leal & Gray (2010). The contribution of carers therefore is making up a major part of the support system for people with dementia (Wimo et al., 2011). The NICE-SCIE Guidelines (2006) and the National Strategy for Carers (Department of Health, 2008), emphasise the importance of addressing the needs of carers of people with dementia.

1.5.2 Carers of people with dementia

Dementia caregiving has become a prominent focus of research within the social sciences. It is well documented that caring for people with dementia is associated with increased psychological distress and burden (Sorensen et al., 2006). Informal caregiving or caring is a term often used to describe someone providing care to a relative, a friend or a neighbour who is unable to care for themselves in everyday activities (Pearlin, Mullan, Semple, & Skaff, 1990).

In dementia care, receiving a diagnosis of dementia causes significant stress for the carer whilst they try to respond and adapt to major changes in their life and the caregiving relationship (Quinn, Clare, Pearce, & van Dijkhuizen, 2008). During the trajectory of dementia, the person with dementia requires high levels of practical assistance with daily tasks due to a progressive decline in memory, loss of abilities in everyday activities and increasing dependence (Brodaty & Donkin, 2009). For example, as dementia progresses, the person requires more assistance with personal care tasks such as getting in/out of bed, dressing, toileting, managing incontinence, bathing and feeding (Alzheimer's Society Report 2015).

Caring for someone with dementia is labour intensive as carers often provide care for long hours which results in difficulties in remaining in employment (Wanless 2006). Consequently, they are financially affected by reduced income, and retirement pension (Wakabayashi & Donato, 2006). Therefore, caring for a family member with dementia can cause excess strain and distress on the caregiving relationship and increase levels of burden for carers (Wang, Shyu, Tsai, Yang, & Yao, 2013).

1.5.3 Quality of life (QoL) in carers of people with dementia

The World Health Organisation defines QoL as an “individual’s perceptions of their position in life in the context of the culture and values systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept, affected in a complex way by a person’s physical health, psychological state, personal beliefs, social relationships and their relationship to their environment” (WHOQOL Group 1994). However, the term QoL has been broadly defined, depending on the scope of evaluating factors concerning personal life and its application by researchers. Despite the different definitions, most researchers consider that QoL is the combination of physical/psychological health, socioeconomic status, life satisfaction and wellbeing (Meeberg, 1993; St John & Montgomery, 2010). Life satisfaction refers to feelings of happiness and contentment regarding life. As a result, it can be considered as an outcome of QoL (Meeberg, 1993).

Carer wellbeing is often conceptualised differently across studies. Physical, psychological, emotional, social or financial resources are perceived as important dimensions of carer wellbeing (George & Gwyther, 1986). Caring for someone with dementia can result in decreased wellbeing due to the impact of cognitive

impairment, behavioural disturbances, family conflict or caring responsibilities (Pearlin et al., 1990). Carer wellbeing is conceptualised in three ways: subjective caregiving stress, subjective feelings of effectiveness, and depressive symptoms (Townsend & Franks, 1995). Carers experience high levels of burden, poor health and reduced wellbeing as a consequence of their caring role when compared with the general population (Pinquart & Sorensen, 2003). Low-rating of carer QoL as a result of poor mental and physical health is a predictor of increased use of health care services (Brodaty & Donkin, 2009). The QoL of carers of people with mild and moderate dementia is related to carer burden and depressive symptoms (Santos et al., 2014).

1.5.4 Health-related quality of life (HR-QoL) in carers of people with dementia

Informal carers play a vital role in dementia care. However, being an informal carer can be detrimental to both the physical and psychological health of carers (Serrano-Aguilar, Lopez-Bastida, & Yanes-Lopez, 2006). While the literature on carer burden and psychological distress has helped researchers to understand the complexities associated with being an informal carer of people with dementia (Brodaty & Donkin, 2009; Schulz & Martire, 2004), it is essential to understand the risks factors that impact carer health and wellbeing and their perceived HR-QoL (Richardson, Lee, Berg-Weger, & Grossberg, 2013). Several instruments have been proposed and developed to measure HR-QoL which can be classified as disease specific or generic. Generic instruments are used across different populations, while disease-specific measures are designed for a particular disease. In the caring literature, generic measures are more prevalent (e.g. SF-36, SF-12 EQ-5D), as they allow comparisons across a wide range of caring populations. HR-QoL is used to evaluate the subjective impact of physical, mental health and the general wellbeing of the person (Brazier et al., 2007). Additionally, physical and mental health in carers of

people with dementia can predict the level of carer burden. Evidence indicates that low-rated HR-QoL (EQ-5D) (Brooks, 1996) in carers is associated with greater burden (van der Lee, Bakker, Duivenvoorden, & Droes, 2015). Older carers often report poorer HR-QoL (Dunkin & Anderson-Hanley, 1998). Carers perceiving their HR-QoL as poor increases the risk of early care home admission of the person with dementia (Argimon, Limon, Vila, & Cabezas, 2005; Vitaliano et al., 2003).

1.5.5 Physical and mental health in carers of people with dementia

Caring for someone with dementia can result in increased physical health complaints (Vitaliano, Zhang, & Scanlan, 2003) and psychological health problems such as fatigue, increased risk of hypertension and cardiovascular disease or increased mortality (Pinquart & Sorensen, 2007; Schulz & Martire, 2004). Carers of people with dementia often tend to neglect their own health needs such as not getting enough sleep or having a poor diet (Vitaliano, Zhang, & Scanlan, 2003). As a result, they may become exhausted or have reduced immune functioning, thereby increasing the risk of health problems (Tremont, 2011) and reduced QoL (Schulz & Martire, 2004; Thomas et al., 2006).

1.5.6 Anxiety and depression in carers of people with dementia

Taking care of someone with dementia at home imposes higher demands on family carers that can result in increased risk of developing anxiety and depressive symptoms (Joling et al., 2010). Depression in carers of people with dementia is often associated with patient behavioural and psychological symptoms and reduced financial income (Kamiya 2014; Mohamed 2010). Several studies report that carers who experience depression and anxiety often report higher levels of burden (Cooper, Katona, Orrell, & Livingston, 2006; Garcia-Alberca et al., 2012; Takai et al., 2009). In addition, high levels of depression in family carers are associated with low

treatment adherence to interventions that target both patient and carer outcomes (Gitlin, Corcoran, Winter, Boyce, & Marcus, 1999). Evidence shows that behavioural disturbances and psychological symptoms of dementia are more stressful for carers than cognitive and functional impairment (Brodaty & Arasaratnam, 2012).

1.5.7 Quality of the caregiving relationship in dementia

Caregiving has a high interpersonal stress component which can adversely affect the relationship quality of the carer and the person with dementia (Quinn, Clare, & Woods, 2009). As soon as the person receives a diagnosis of dementia, the caregiving relationship takes on new roles to accommodate care demands (Robinson, Clare, & Evans, 2005). This change of roles may have a significant impact on the quality of the relationship (Quinn, Clare, Pearce, & van Dijkhuizen, 2008). Carers living with the person with dementia often report being overwhelmed with their caring role due to providing more hours of caregiving in comparison with carers not living together with their relative (Kim, Chang, Rose, & Kim, 2012). Several studies suggest that the quality of the caregiving relationship prior to the onset of dementia is an important predictor of depression, quality of life, and caregiving satisfaction in carers (Kramer, 1993). Having closeness or conflict in the relationship prior to the onset of dementia can influence the current relationship and impact on carers' wellbeing (Quinn et al., 2009; Townsend & Franks, 1995). During the trajectory of dementia, losses in the ability to perform activities of daily living can change the needs of the person with dementia. For example, the person with dementia often experiences difficulties in communication and learning new information which leads to withdrawal from hobbies and everyday activities (Potkin, 2002).

Due to the progressive loss of cognitive and functional abilities and presence of behavioural disturbances associated with dementia, the person becomes more

dependent on their carer (Quinn et al., 2009). Carers therefore must spend a substantial amount of time to meet care demands, thus affecting their access to social activities, leading to social isolation. Decreased cognitive function and increased behavioural disturbances in the person with dementia are associated with poor quality in the caregiving relationship (de Vugt et al., 2003; Spruytte, Van Audenhove, Lam-mertyn, & Storms, 2002). Poor relationship quality contributes to further losses of the carers' functional ability and negatively affects the person with dementia's wellbeing (Ablitt, Jones, & Muers, 2009). As a result, it can often lead to short-term or long-term hospital or care home admissions which can be costly for health care services (Knapp, Lemmi, & Romeo, 2013).

Although caring for someone with dementia poses an enormous negative impact on the quality of the caregiving relationship, which limits carers' ability to care for their relative (Adams, McClendon, & Smyth, 2008), caregiving can also provide carers with opportunities to express love, care and emotional support (Cartwright et al., 1994). These bonds that tie carers with their loved ones (Motenko, 1989) and protect them from high levels of role strain can improve the caregiving relationship (Yang, Liu, & Shyu, 2014). Closeness in the caregiving relationship is associated with positive outcomes for the person with dementia and increased wellbeing in carers (Townsend & Franks, 1995). High levels of mutuality may reduce role strain in carers of people with mild dementia (Yang, Liu, & Shyu, 2014). Role strain is often caused by family conflict on relationship quality and reduced social life outside of the caregiving role (Pearlin, Mullan, Semple, & Skaff, 1990). Mutuality is described as the perceived relationship between the person and their carer and the extent to which they share meaningful and pleasurable activities (Archbold, Stewart, Greenlick & Harvath, 1990). Since the caregiving relationship in dementia is associated with interpersonal stress, it is vital to consider using interpersonal relationship strategies

such as positive attitudes towards the caregiving relationship to build and sustain mutuality in the relationship (Kramer, 1993). Carers who report a positive caregiving relationship with their relative, experience fewer burdens, and are more likely to describe caregiving as a meaningful experience (Quinn, McGuinness & Woods, 2012).

1.6 Psychosocial interventions for carers of people with dementia

Increasing research has been conducted to gain a better understanding of the impact of caregiving distress and burden on carers and develop interventions to support their needs. Examining the effects of psychosocial interventions is essential in improving practical and social support for carers of people with dementia (Yu et al., 2012), which in turn contributes to the cost-effectiveness of dementia care (Knapp, Lemmi, & Romeo, 2013). Several psychosocial interventions have been developed to support carers of people with dementia. These interventions can be broadly categorised into: a) psycho-education, b) supportive interventions, c) counselling and d) multicomponent interventions (Parker, Mills, & Abbey, 2008).

1.6.1 Psycho-educational interventions for carers of people with dementia

Psycho-educational interventions often involve structured programmes which provide information about dementia and information on available resources and services for carers. They often incorporate skills training such as coping with the behavioural and psychological symptoms of dementia and increasing problem-solving and decision-making skills (Brodaty, Gresham, & Luscombe, 1997; Burns, Nichols, Martindale-Adams, Graney, & Lummus, 2003; Mittelman, Roth, Coon, & Haley, 2004; Teri et al., 2003). Cognitive behavioural therapy (CBT) techniques are often used in psycho-educational interventions for carers, which additionally target negative emotions and teach carers specific skills to cope with stress (Scott et al.,

2015). A review by Pinquart and Sorensen (2006) evaluated the effects of psychoeducation, CBT and counselling interventions for carers and found that psycho-educational interventions decreased carer burden and depressive symptoms.

1.6.2 Carer supportive interventions

Supportive interventions, on the other hand, provide opportunities for carers to share their experiences, feelings and access emotional support which can reduce social isolation (Hebert, Leclerc, Bravo, Girouard, & Lefrancois, 1994). Evidence shows that attending carer support groups was beneficial for carers in terms of gaining a better understanding of dementia, developing coping skills and accessing peer support (Bailey, Kingston, Alford, Taylor, & Tolhurst, 2016). Gallagher-Thompson & Coon (2007) suggest further research to explore the effects of support interventions for carers at different 'stages' of caring.

1.6.3 Carer counselling interventions

Counselling interventions are also found to be effective in reducing burden and improve carers' mental health (Pinquart & Sørensen, 2006). Recently Livingston and colleagues (2013) evaluated the effects of a structured psychological intervention for carers of people with dementia consisting of psycho-education, emotional support, coping and relaxation skills. The study found that carers taking part in the intervention reported lower levels of depressive symptoms, and had better mental health outcomes after a two-year follow-up. While a number of studies indicate that carer burden can be alleviated through interventions that directly focus on carers (Donaldson and Burns 1999), only a few studies have examined the benefits of carer involvement in CBTs for people with dementia (Clare et al., 2010a; Onder et al., 2005; Orgeta et al., 2015; Quayhagen et al., 2000).

1.6.4 Carer multicomponent psychosocial interventions

Multicomponent psychosocial interventions for carers often combine education, counselling support, problem solving, and skills training (Kales, Gitlin, & Lyketsos, 2015). Gaugler, Roth, Haley, & Mittelman (2008) conducted a multicomponent RCT to examine the effects of counselling and support for carers of people with dementia on carer burden and depressive symptoms during transition to institutionalisation. The findings of this multicomponent intervention showed that carer burden and depressive symptoms were significantly reduced in the treatment group in comparison to the control group at the time of and after institutionalisation.

Furthermore, several studies have shown that psychosocial interventions for family carers of people with dementia may delay institutionalisation for people with dementia (Brodaty, Green, & Koschera, 2003; Mittelman, Ferris, Shulman, Steinberg, & Levin, 1996; Selwood, Johnston, Katona, Lyketsos, & Livingston, 2007).

2 Chapter 2 Development of a theoretical framework of carer involvement in CBIs for people with dementia

2.1 Background of developing a theoretical framework of carer involvement in CBIs

The aim of this chapter is to present a clear and accessible framework for understanding the influence of carer involvement in CBIs for people with dementia that guides the development of my PhD research and links with my findings. Firstly, I highlight the differences between caring in general and caring specifically for people with dementia, and the key factors associated with changing roles in dementia caregiving. I also report on recent key policies for people with dementia and their family carers specifically in relation to promoting early diagnosis that aims to provide better access to care for people with dementia and their families. Secondly, I present my understanding of carer stressors in dementia caregiving and its impact on carer wellbeing by using the Stress Process Model (SPM) of Pearlin (1990) and modifying the SPM to accommodate mediators of dyadic interpersonal interactions (mutual sharing of pleasurable and meaningful experiences, mentally stimulating activities and cognitive support by carers). Thirdly, I present the process of deriving the three key elements of the theoretical framework of carer involvement in cognition-based interventions (CBIs) and the rationale for their selection over other theories.

2.1.1 Differences between general caregiving and dementia caregiving

Dementia is a chronic disease of the brain where people with dementia may need high levels of practical assistance with daily tasks due to cognitive decline, loss of communication and abilities in everyday activities and increased dependence (Brodaty & Don-kin, 2009). Research on dementia caregiving has identified the differences between dementia caregiving and generic caregiving and has shown that caregiving has greater impact on dementia carers than non-dementia carers in a

variety of domains. Evidence has shown that carers of people with dementia often experience increased psychological distress, burden, greater caregiving intensity, and feelings of isolation in the caregiving role in comparison to other carers (Bertrand, Fredman, & Saczynski, 2006; Brodaty & Donkin, 2009; Sorensen, Duberstein, Gill, & Pinquart, 2006). They are more likely to be involved in intensive hours of caregiving due to increased care demands which subsequently lead to a loss of freedom (Bertrand et al., 2006; Papastavrou, Kalokerinou, Papacostas, Tsangari, & Sourtzi, 2007).

Caring for a person with dementia requires not only practical personal care but also emotional support and managing cognitive impairment as well as behavioural and psychological symptoms of dementia (e.g., verbal aggressiveness, agitation, sleep disturbances) (Shah 2010). Some carers report that managing behavioural problems in dementia can be the most difficult caregiving activity (Huang et al., 2015). Carers of people with dementia may experience higher levels of strain than non-dementia carers because they are more likely to have to manage associated neuropsychiatric symptoms such as depression and apathy (Anor et al., 2017; Brodaty & Donkin, 2009; Lyketsos & Olin, 2002). During the dementia trajectory, carers may experience multiple losses such as loss of companionship, personal freedom and control (Chan, Livingston, Jones, & Sampson, 2013). Evidence shows that carers of people with dementia experience greater level of anticipatory grief than non-dementia carers (Ross and Dagley, 2009). As the disease progresses, anticipatory grief is exacerbated, especially at the later stages of dementia where there is a loss of communication and changes in personality posing carers at higher levels of distress (Large & Slinger, 2015).

2.1.2 Changing roles of carers of people with dementia

The majority of people with dementia are cared for at home by family carers (Alzheimer Research UK, 2012) such as spouses, parents, siblings, adult children, other members of the family, friends and neighbours (Pearlin, Mullan, Semple, & Skaff, 1990). Dementia can have a significant impact on the roles and relationships of people with dementia, their carers, other members of the family and the wider social network of individuals (Quinn, Clare, & Woods, 2015). Carers may have to adjust to changes in the relationship, undertake new roles previously fulfilled by the person with dementia and take responsibilities to accommodate care demands (Robinson, Clare, & Evans, 2005). Some carers express difficulties in adjusting to their new responsibilities (Quinn, Clare, Pearce, & van Dijkhuizen, 2008) as they may struggle to manage between keeping the person with dementia safe and supporting their independence such as encouraging them to be involved in activities (Bunn et al., 2012; Catherine Quinn, Clare, & Woods, 2015).

As the disease progresses the person with dementia may experience neuropsychiatric symptoms such as wandering, agitation, hallucinations, or sleeping and eating difficulties and carers may face multiple demands to cope with these symptoms (Pearlin et al., 1990). Changing of roles is emotionally challenging for carers and can have a significant impact on the caregiving relationship and carers' perception of the quality of the caregiving relationship (Quinn, Clare, Pearce, & van Dijkhuizen, 2008). Carers may experience many dilemmas in their role as they try to balance both their needs and the needs of their relative. For example the loss of a mutually supportive relationship can cause an imbalance in the relationship as carers have to prioritise the needs of their relative (Quinn et al., 2015).

On the other hand reversing of roles can lead carers with opportunities to take responsibility of all the decisions allowing them to feel empowered but also greater distress (Quinn et al., 2008). However, for some couples shifting roles and responsibilities tend to result in them having to spend more time together as dementia progresses, rather than being able to spend time on their own independent activities (La Fontaine & Oyebode, 2014).

2.1.3 The rights based agenda and policies for people with dementia and their family carers

Being diagnosed with dementia can have a significant impact on the daily life of people with dementia and place the person with dementia and their family in a highly stigmatised social group (Pesonen, Remes, & Isola, 2013). In recent years, access to early diagnosis and support have increasingly emerged as key policy priorities in National Health Services (NHS) in England and other countries via the development of National Dementia Strategies (Prince et al., 2011). The Prime Minister's Challenge on Dementia emphasised the need of early diagnosis for people with dementia enabling them to access appropriate treatment, receive information, advice and support (Department of Health 2012). Early diagnosis allows the person with dementia to plan for their future while they still have the capacity to make important decisions about their care plan and their family carers being provided with opportunities to receive information and practical support (Prince et al., 2011). Economically, early diagnosis can help to delay institutional admission, improve physical and mental health and QoL for both people with dementia and their carers which lowers health care costs (Burns, 2012).

It is important to identify and promote best care practice in the early stages of dementia to enhance wellbeing for patients and their families. The NICE-SCIE

Guidelines (2006) and the National Strategy for Carers (Department of Health, 2008), emphasise the importance of addressing the needs of carers of people with dementia such as the rights of carers to receive an assessment of their needs, being offered psychological therapy, such as cognitive behavioural therapy, conducted by a specialist practitioner. In terms of practical support and services, health care services should ensure that carers of people with dementia have access to a comprehensive range of respite/short break services. These services should meet the needs of both the carer and the person with dementia (National Collaborating Centre for Mental, 2007).

2.1.4 The Stress Process Model (SPM) of dementia caregiving

Several theoretical models have been developed to explain the process of caregiving stressors and their effects on outcomes for carer wellbeing (Lazarus & Folkman, 1984; Sorensen, Duberstein, Gill, & Pinquart, 2006; Yates, Tennstedt, & Chang, 1999). The Stress Process Model of Pearlin et al., (1990) is one of the most comprehensive and influential models of dementia caregiving. Pearlin and colleagues (1990) propose four main domains that explain the dementia caregiving stress process, which includes the background and context of the stress process, the stressors, the mediators and carer outcomes (Figure 2.1). Stressors in this model are categorised into three subgroups that comprise primary stressors that are assessed by objective and subjective factors, secondary role strains and secondary intrapsychic strains.

2.1.4.1 Background and context of the stress process

The background and context of the stress process highlights the consequences of caregiving that is influenced by characteristics of the carer such as age, gender, ethnicity, along with educational, occupational, economic status, and composition of

social networks. For example, older carers often experience high levels of carer burden due to physical limitations, while younger carers are at greater risk of experiencing depression due to financial losses, social and family strain (Schoenmakers, Buntinx, & DeLepeleire, 2010). Education influences the strategies that carers choose to manage the patient's functioning (De Vugt et al., 2004) and is associated with subjective burden in carers in some studies (Sink, Covinsky, Barnes, Newcomer, & Yaffe, 2006). Poysti and colleagues (2012) examined gender differences in dementia spousal carers and found that male carers experienced lower burden in comparison to female carers even if their relative's dementia was more severe. Socioeconomic status can also influence carer burden and wellbeing. Carers with larger social networks and higher economic status experience less stress, partly due to having better access to health care systems (Brodaty, Thomson, Thompson, & Fine, 2005). Carers living with the person with dementia may report worse health, loss of independence and reduced social life compared to carers not living with their relative (Cox & Albis 2003).

2.1.4.2 Objective and subjective primary stressors

The primary stressors are related to both objective and subjective factors. Objective factors of primary stressors are an indicator of current care demands posed by the dementia that change over time during the trajectory of disease. The primary objective factors are assessed by the person's cognitive status, problematic behaviours, and degree of dependency of everyday activities. Severity of psychiatric and behavioural disturbances along with decreased quality of life of the person with dementia are associated with higher levels of burden and depression in carers (Mohamed, Rosenheck, Lyketsos, & Schneider, 2010; Pinquart & Sorensen, 2003).

Subjective primary stressors refer to carers' psychological and emotional consequences driven by the impact of objective stressors such as levels of cognitive impairment or behavioural disturbances in the person with dementia. Subjective stressors can also influence the caregiving relationship (Anderson, Towsley, & Gaugler, 2004). Carers often find it difficult when care intensity is high and perceive fewer benefits about caring (Sorensen et al., 2006). It is important to identify and understand the differences between objective and subjective primary stressors and their impact on carers' perception and appraisal of these stressors which may change over time.

2.1.4.3 Secondary stressors

Role strains and intrapsychic strain are considered as secondary stressors because they occur as a direct result of primary stressors (Pearlin et al., 1990). Secondary strains include role strain such as family conflict, work, economic problems and social life that is affected by providing care for someone with dementia. For example, carers often provide care for long hours, due to the progressive nature of the disease (Wanless 2006). The caregiving relationship is constantly changing as a result of increasing care demands and because of the progression of the disease. Role overload on the other hand can affect carers' self-esteem, sense of control and self-identity (Pearlin et al., 1990).

Secondary stressors also manifest as internal self-perceptions and feelings which are referred to as intrapsychic strains. As described by Pearlin and colleagues (1990), intrapsychic strains can be further conceptualised as global or situational intrapsychic strains. Global strains reflect internal characteristics of the carer such as self-esteem and mastery. Conversely, situational intrapsychic strains are less enduring and vary depending on the context of a person's experience, such as self-

efficacy in maintaining activities or relationships. In the context of caregiving, self-efficacy refers to the individual's beliefs on his/her ability to cope adequately when encountering problems and taking actions to meet the particular demands of the situation. Carer self-efficacy may change over time in response to specific caring role experiences (Au et al., 2009). Experiencing high levels of self-efficacy can protect carers from experiencing high levels of burden (Contador, Fernandez-Calvo, Palenzuela, Migueis, & Ramos, 2012).

2.1.4.4 Mediators of stressors

In this model, coping strategies and seeking social support act as mediators which directly influence primary and secondary stressors and indirectly impact on carer outcomes. The application of coping strategies includes management of the situation giving rise to stress, management of the meaning of the situation and management of the stress symptoms. For example, carers who endorse dysfunctional coping strategies experience higher levels of burden (Papastavrou, Kalokerinou, Papacostas, Tsangari, & Sourtzi, 2007) and anxiety (Cooper, Katona, Orrell, & Livingston, 2006; Cooper et al., 2012).

Carers of people with dementia often experience feelings of social isolation, lack of social contact as well as social support (Brodaty & Hadzi-Pavlovic, 1990; Serrano-Aguilar, Lopez-Bastida, & Yanes-Lopez, 2006). Therefore, social support is proposed as a mediator between the background context and carer outcomes. Two types of social support are assessed in this model which includes instrumental and expressive support. The availability of instrumental support is measured by items asking whether there is someone who assists the carer in the care of their relative or who helps with household chores. Expressive social support evaluates the extent to which a person is perceived in caregiving as caring, trustworthy, uplifting and

having a confidant. Social support may positively affect carers' health by reducing carer stressors and helping carers to develop and maintain effective coping strategies (Haley, Levine, Brown, & Bartolucci, 1987).

2.1.4.5 Carer outcomes

The SPM considers a broad range of outcomes related to carer wellbeing that includes physical and mental health. Outcomes of carers' physical health comprise limitations in their ability to engage in everyday activities. The outcomes of carers' mental health include depression, anxiety and cognitive disruptions. These outcomes are the direct result of the complex interaction between the SPM background and context factors of carer characteristics, primary and secondary stressors and mediators.

2.1.4.6 Conclusion

The SPM serves as a useful heuristic for understanding stressors in caregiving in dementia. The SPM's application of the background and context domain variables includes aspects of the caregiving history such as current and past conflict in the caregiving relationship between the carer and the person with dementia which directly impacts on multiple stressors, coping strategies and social support. In this model, stressors are caused by negative symptoms of progression of dementia. These stressors interact and impact on wellbeing outcomes. Coping strategies and social support act as mediators between the background context, the multiple stressors and carer outcomes. The SPM, therefore, provides a useful framework to identify predictors of carer stress and guide interventions that aim to limit or minimise primary or secondary stressors associated with the dementia caregiving process by enhancing carers' coping skills (Oyebode, 2003).

Although the SPM has been highly influential in dementia caregiving research in the past decades, it has been criticised for its lack of consideration of the dyadic interpersonal relationship and for focusing mainly on negative outcomes of caregiving. Pearlin and colleagues (1990) acknowledge that the stress process model has its limitations and suggest that the SPM should be considered as “a model” that researchers can build upon rather than something to be followed or perpetuated as originally developed.

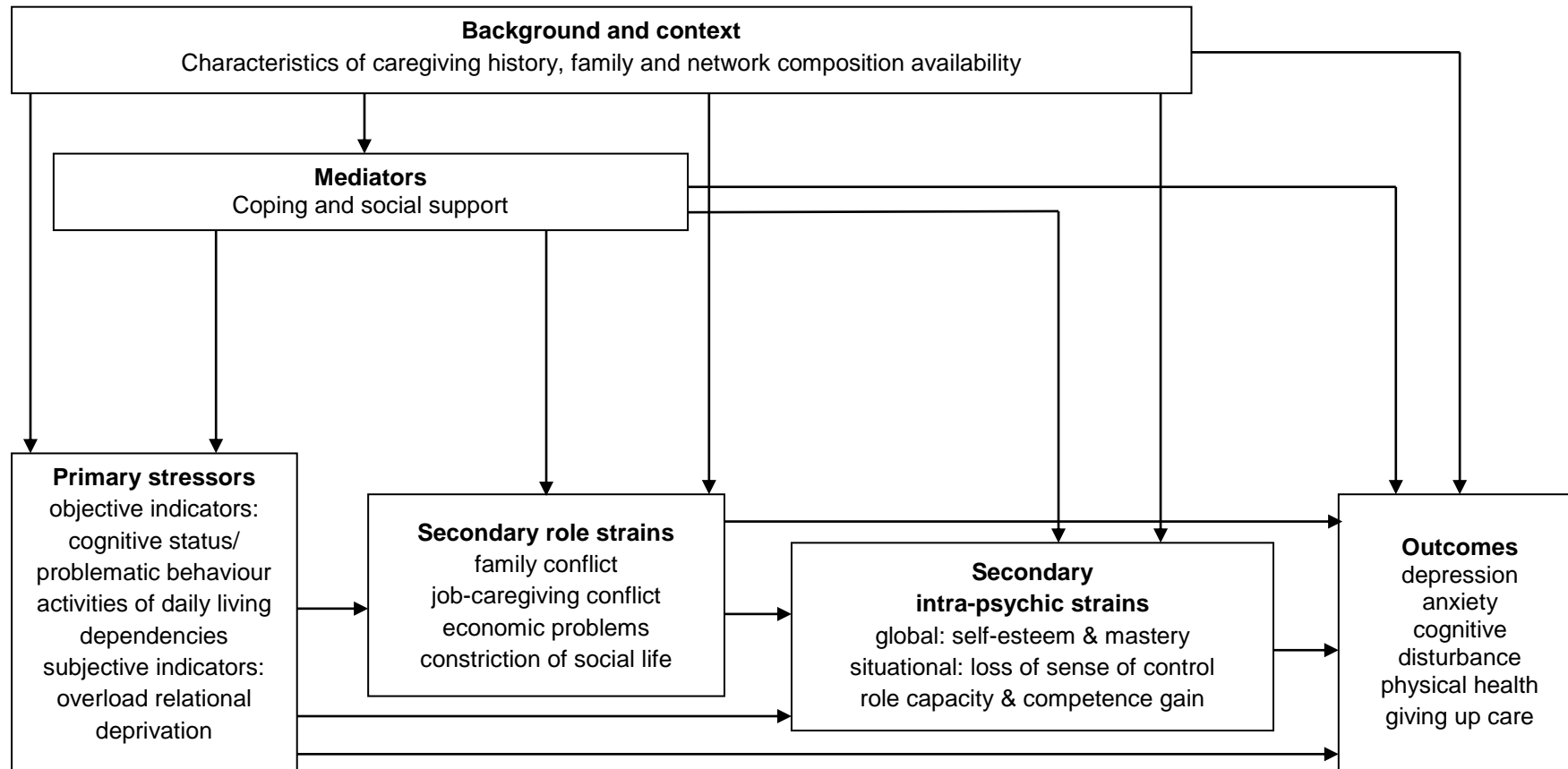


Figure 2.1 Caregiving Stress Model (Pearlin 1990)

2.2 Carer involvement in CBIs for people with dementia: Theoretical perspectives

2.2.1 Overview of carer involvement in CBIs

CBIs predominantly focus on improving cognition for people with dementia (Clare et al., 2010; Neely, Vikstrom, & Josephson, 2009; Spector et al., 2003). However, it has recently been suggested that this focus needs to be broadened to include family carers (Gitlin & Earland, 2010). A recent review showed that engaging carers in psychosocial interventions may increase mutual understanding and enhance the caregiving relationship (Moon & Adams, 2013). Taking part in CBIs provides an environment for carers to interact and understand the cognitive needs of the person with dementia and thus increase their cognitive support (Gitlin & Earland, 2010). For example, carer' participation in reality orientation sessions provide them with opportunities to engage with the person with dementia in reality-based communication and focus on the person's cognitive needs by discussion of personal, time and space orientation, current affairs and topics of general interest (Onder et al., 2005). However, the inclusion of carers in CBIs can be very challenging as carers may report increased depressive symptoms when they participate in interventions alongside their relative (Zarit, Zarit, & Reever, 1982).

The SPM of dementia caregiving has been widely used in research examining stress and coping in family carers (Aneshensel et al., 1995; Gaugler et al, 2000; Pearlin et al., 1990). It proposes that social support and carers' coping strategies are two principal mediators of the relationship between carer stress and carer wellbeing (Pearlin et al., 1990). However, the SPM does not explicitly state how dyadic interpersonal interactions between the carer and the person with dementia could act as a mediator to buffer the impact of stressors (Sanders, 2005; Zarit, 2012). In order to examine the effects of carer involvement in CBIs, it is important to consider the interpersonal aspects of the caregiving relationship. For example, the positive effects of caregiving include feelings of reward, enjoyment and gratification (Kramer, 1997), whereas negative experiences include lack of motivation in the context of the caregiving relationship (Ablitt 2010). Due to this lack of dyadic interpersonal

interactions in the SPM (Pearlin et al., 1990) (Figure 2.1), I revised this model to accommodate three key components (Figure 2.2) that include a) dyadic interpersonal interactions in the caregiving relationship, b) opportunities to engage in pleasurable and meaningful activities and c) cognitive support provided by carers as potential mediators of the SPM of dementia caregiving. I have further developed and conceptualised a framework of carer involvement in CBIs (Figure 2.3). The theoretical underpinnings of this model lie in the binding ties theory (Townsend & Franks, 1995), the enrichment process theory (Cartwright, Archbold, Stewart, & Limandri, 1994) and the scaffolding process theory (Cavanaugh et al., 1989).

2.2.2 Theoretical perspectives

A theoretical framework was required in order to have a better understanding of the processes of carer involvement in CBIs for people with dementia and help to develop the intervention that focuses on enhancing carer wellbeing and the quality of the caregiving relationship. This theoretical framework was developed through a consideration of models that focus on positive aspects of carer involvement in psychosocial interventions for people with dementia as well as their potential impact on carer wellbeing.

During the literature search, I identified several pre-existing theories which included: 1) the activity theory (Havighurst 1961), 2) the attachment theory (Bowlby 1969), 3) the binding ties theory (Townsend & Franks, 1995), 4) the enrichment process theory (Cartwright, Archbold, Stewart, & Limandri, 1994) and 5) the scaffolding process theory (cognitive support) (Cavanaugh et al., 1989). These theories illustrate elements of interpersonal interactions, share the focus on engaging in activities and the caregiving relationship.

After evaluating the characteristics of these theories (Table 2.1), the activity theory and attachment theory were excluded as potential models of the theoretical framework of carer involvement in CBIs. Although the activity theory focuses on being active and promoting

successful aging, it is limited in relation to the meaning of specific activities for individuals, as it mainly focuses on social interactions rather than dyadic personal interactions. The attachment theory focuses on positive and insecure attachments, for example, a secure attachment bond provides a source of comfort and assistance, whilst an insecure attachment leads to increased dependency (Miesen, 1993). Therefore, the attachment theory lacks a focus on dyadic personal interactions in terms of mutually sharing meaningful experiences and mentally stimulating activities.

The binding ties theory (Townsend & Franks, 1995), the enrichment process theory (Cartwright, Archbold, Stewart, & Limandri, 1994) and the scaffolding process theory (Cavanaugh et al., 1989) were applied to a framework of carer involvement in CBIs for people with dementia (Figure 2.3). These theories were included because they incorporated dyadic interpersonal interactions in dementia caregiving such as positive aspects of mutual sharing of pleasurable and meaningful experiences, mentally stimulating activities and providing cognitive support to people with dementia. For example, the quality of the caregiving relationship between carers and the person with dementia is considered as playing an important role in the dynamics of caregiving and is identified as a central domain of the caregiving experience (Townsend & Franks, 1995). Cartwright and colleagues (1994) have proposed a link between the quality of the relationship and the pleasurable enrichment process by highlighting how the quality of the previous and current relationship could influence caregiving stress. As dementia is a progressive disease, Cavanaugh and colleagues (1989) have applied the scaffolding process theory, which emphasises the importance of carers' cognitive support to the person with dementia which can contribute to enhancing interpersonal interactions, thereby contributing to increased wellbeing for both carers and people with dementia. The next section describes each of the three theories and their key components in more detail.

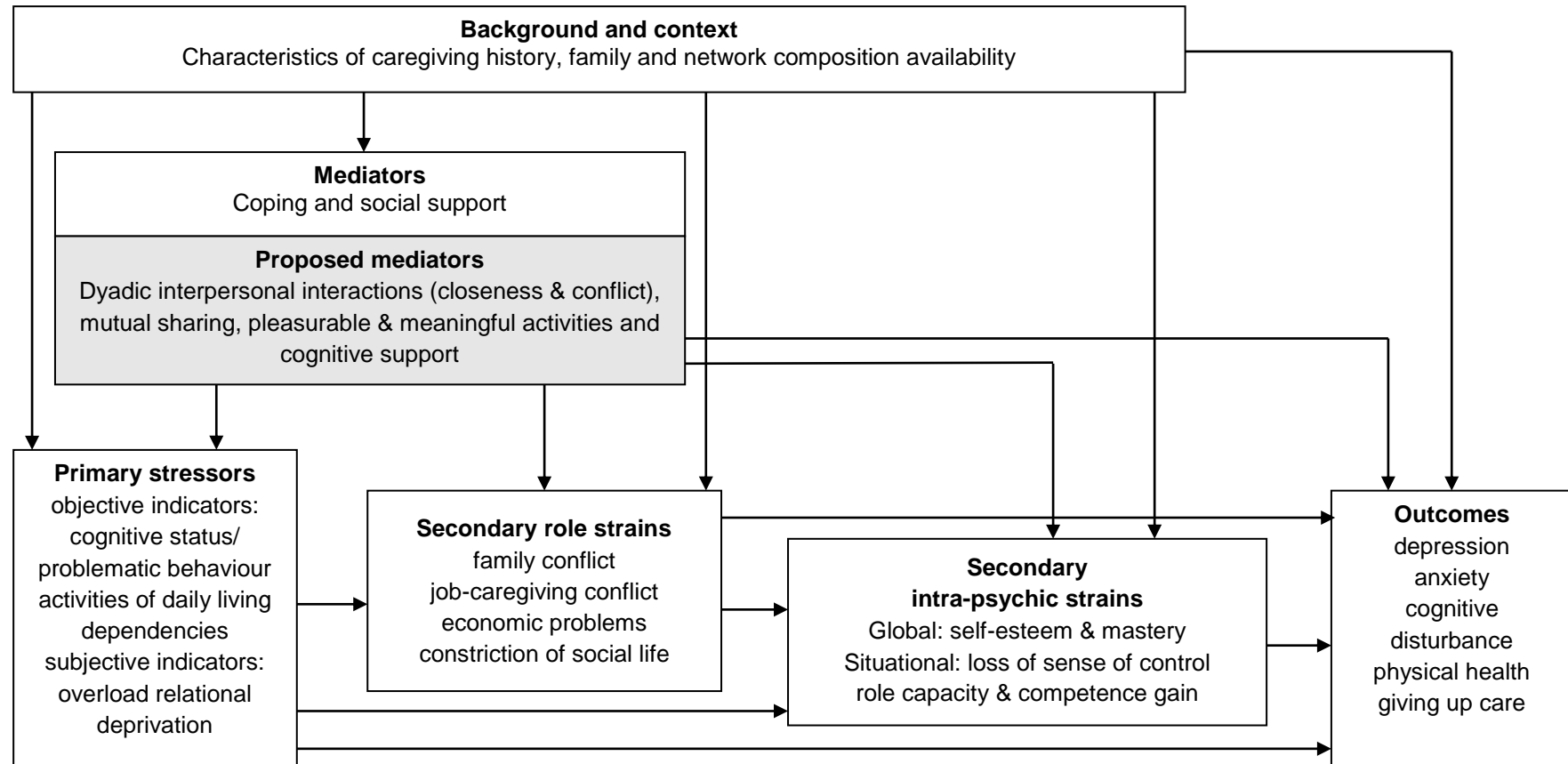


Figure 2.2 Caregiving Stress Model Revised (Pearlin 1990)

Table 2.1 Characteristics of principal theories of carer involvement in cognition-based interventions

Theories	Characteristics	Inclusion	Exclusion
Activity theory (Aging) (Havighurst 1961)	An assumption that social interaction is important for older adults and that older people who are more active maintain social interaction	1) Being active and ageing successfully 2) Maintain social interactions	1) Focuses on social interaction. 2) lacks mutual sharing of pleasurable, meaningful and mentally stimulating activities 3) lacks dyadic interpersonal interaction elements.
Attachment theory (Bowlby 1969)	Bowlby's original attachment theory (1969) focusing on the relationship between infants and their carers and associated responses during brief separation.	1) Attachment bond 2) Positive attachment 3) Providing a source of comfort and assistance.	1) Focuses on insecure attachment that leads to increased dependency Miesen (1993) 2) Lacks mutual sharing of pleasurable and meaningful activities and elements of dyadic interpersonal interaction.
Binding ties theory (Townsend & Franks, 1995)	The quality of caregiving relationship between the person with dementia and their adult child carer described as a mediator between cognitive impairment, and carer wellbeing.	1) Dyadic interpersonal interaction 2) The quality of caregiving relationship 3) Closeness and conflict	

Enrichment process theory (Cartwright et al., 1994)	Process of mutual sharing of pleasurable meaningful experiences and activities.	<ol style="list-style-type: none"> 1) Dyadic interpersonal interaction 2) the quality of the caregiving relationship 3) Mutual understanding, sharing pleasurable and meaningful experiences and activities
Scaffolding process theory (Cavanaugh et al., 1989)	Process of cognitive support by carers	<ol style="list-style-type: none"> 1) Dyadic interpersonal interaction 2) Sensitive to the person with dementia cognitive needs. 3) Cognitive support 4) The quality of caregiving relationship.

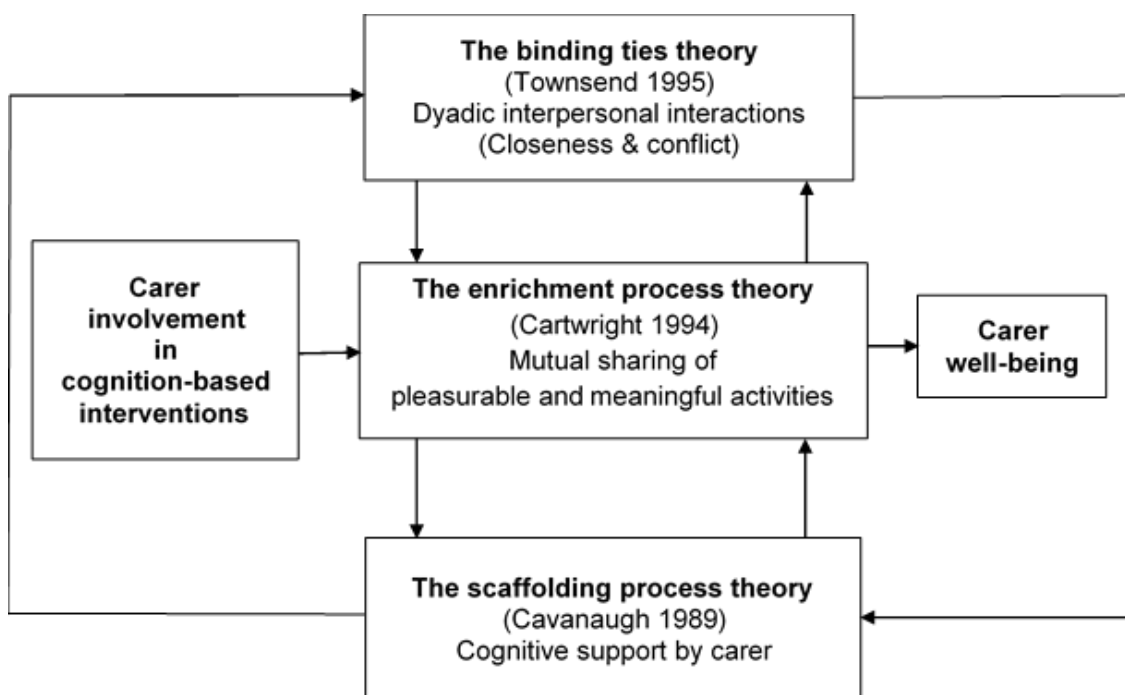


Figure 2.3 A theoretical framework of carer involvement in CBIs for people with dementia

2.2.3 A theoretical framework of carer involvement in CBIs for people with dementia

2.2.3.1 Binding ties theory

Most of the dementia caregiving relationship literature has focused on the negative experiences of caring (Pearlin et al., 1990; Pinquart & Sorensen, 2003). A negative caregiving relationship is considered as one that is critical, confronting and characterised by diminished communication (Kramer, 1993). In the context of dementia caregiving, several studies emphasise on the importance of a positive relationship and mutuality, affection and intimacy between people with dementia and their carers (Archbold, Stewart, Greenlick, & Harvath, 1990; Walker, Martin, & Jones, 1992). Positive caregiving relationship strategies refer to negotiation, compromise, considering the other person's limitations, empathy and compassion (Kramer 1993). Closeness was assessed with feelings of affirmation (e.g., "My parent understands what I value in life"), affection (e.g., "My parent is affectionate towards me") and fundamental facets of intimate ties (House & Kahn, 1985; Reis & Shaver, 1988).

Conflict was measured by frequency of communicating negative affect, negative evaluations, or social undermining (Reis & Shaver, 1988; Vinokur & van Ryn, 1993). Carers' wellbeing was measured by subjective caregiving stress (Townsend, Noelker, Deimling, & Bass, 1989) and subjective caregiving effectiveness (Townsend et al., 1989). Depressive symptoms were assessed by the Self-Rated Depression Scale (Zung 1965).

In line with the binding ties theory (Townsend & Franks, 1995) findings indicated that cognitive decline was more consistently associated with the quality of the caregiving relationship compared to functional decline, which influenced carer wellbeing. Greater cognitive impairment was significantly related to both lower closeness and higher conflict in the caregiving relationship. Functional impairment was not significantly related to either closeness or conflict. The two mediators, closeness and conflict were significantly and strongly correlated with each other in a negative direction; higher levels of conflict were related to feeling less close to the parent (Figure 2.4). Correlations between the two mediators and the wellbeing measures showed that greater closeness was significantly associated with lower stress and depression in carers. Townsend and Frank (1995) suggested that interpersonal interactions provided opportunities for carers to renegotiate and evaluate their affective bonds with their relative in the context of cognitive decline (George & Gwyther, 1986; Zarit et al., 1980). For example, carers identify the cognitive needs of the person and adjust their expectations and goals accordingly to meet their needs.

To conclude, Townsend and Frank (1995) highlight the importance of positive and negative interpersonal interactions to understand the caregiving relationship (Rook, 1990; Walker et al., 1992). However, negative ties were more consistently and

strongly predictive of carer wellbeing than positive ties. Closeness and conflict may differentially affect marital relationships versus relationships between parents and their adult children (Pearlin & Turner, 1987).

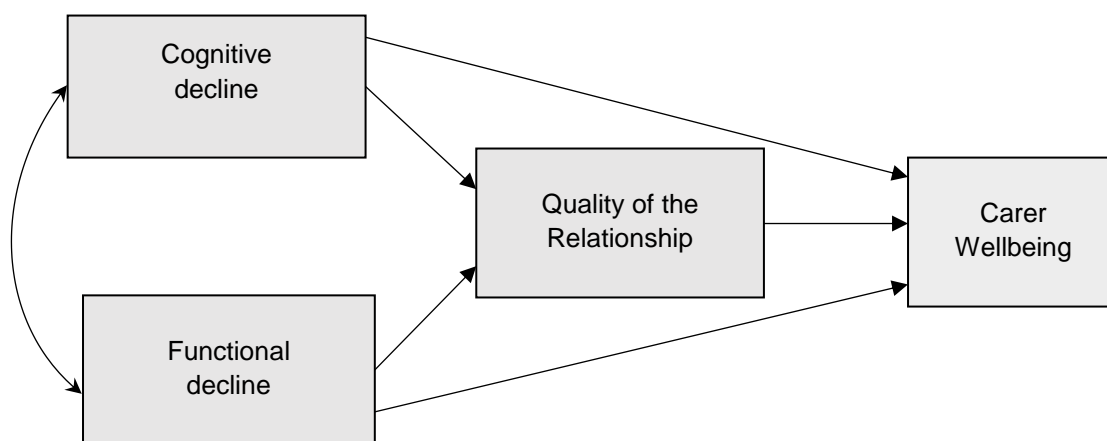


Figure 2.4 A model linking cognitive decline, relationship quality and carer wellbeing

2.2.3.2 Enrichment process theory

Research has increasingly recognised family caregiving as a complex and multifaceted phenomenon. The dementia caregiving literature suggests that mutuality is associated with positive relationships and lowers levels of carer strain (Archbold, Stewart, Greenlick, & Harvath, 1990; Hirschfeld 1983). Cartwright and colleagues (1994) applied a theory of enrichment in family caregiving that explains how some families use pleasurable and meaningful experiences to adapt and cope with the caregiving role. Their study investigating the enrichment process recruited 20 dyads of family carers, people with dementia and frail older people to take part in interviews and observations. Two categories of enrichment processes emerged from their original study which included antecedent factors and consequences of enrichment. The antecedent factors referred to the personal history, fragility trajectory and the quality of the caregiving relationship before enriching events take

place. Consequences of enrichment included carer rewards and the nature of the dyadic relationship after the enrichment process.

Core elements of the enrichment process included acquiring symbolic meaning, performing an activity, and fine tuning. Acquiring symbolic meaning referred to meaningful activities, events, experiences or something people value and may change over time. For example, a carer described an experience of singing duets with their relative with dementia that helped to bring back memories. Performing activities was described as observable behaviour in caregiving situations where the person with dementia and the carer had an opportunity to interact. For example, the person with dementia and carer both prepared their lunch, but each had a specific role such as the carer prepared the lunch and the person with dementia set the table. Therefore, they had a different role in the activity, but they interacted and achieved the same goal. Fine tuning was the process of adapting activities to accommodate the person's cognitive abilities and needs. For example, a dyad demonstrated fine tuning by accommodating the annual camping family holiday and visiting friends by changing it into a day trip, because the person with dementia had multiple functional limitations (Cartwright et al., 1994)

In accordance to the enrichment process, the interpersonal interactions between people with dementia and their carers are crucial because they provide opportunities to reflect on the past and current knowledge, share values and meaningful experiences. In positive dyadic relationships, dyads are more likely to share pleasurable activities and enjoy doing things together. Conversely, in less positive caregiving relationships, carers may experience greater distress and burden, and feeling of resentment about their caring role (Ablitt, Jones, & Muers, 2010). This increases the likelihood of negative feelings such as responding with frustration or

withdrawal which can further decrease and threaten the caregiving relationship (de Vugt et al., 2003).

2.2.3.3 Scaffolding process theory

Cavanaugh, Grady, and Perlmutter (1989) used the theory of proximal development (Vygotsky 1978) and scaffolding theory (Bruner 1975) to develop a model of cognitive support in the context of dementia caregiving. Vygotsky (1978) identified a gap between a child's current performance, potential performance and the consequences if that child was given guidance by someone more skilled. Vygotsky (1978) termed this gap the "zone of proximal development" where a more knowledgeable person to the 'learner' could provide structure and direction to increase the functional performance of the learner's ability. Bruner (1975) proposed the theory of cognitive support which was named as "scaffolding".

Cavanaugh, Grady, and Perlmutter (1989) applied the zone of proximal development (Vygotsky 1978) and scaffolding theory (Bruner 1975) to develop a care model in which carers provide cognitive support systems to their relative. Cavanaugh and colleagues (1989) recruited twenty-nine dyads of people with dementia and their carers to investigate the effects of the cognitive support system. During the cognitive support process, people with dementia and carers worked together to complete assembling blocks of the Wechsler Adult Intelligence Scale-Revised (WAIS-R). This is a complex block building test examining nonverbal reasoning capacity which required to assemble the designed blocks correctly. Carers were free to use any instructions they thought were appropriate and give explicit directions to people with dementia, in order to engage them in the task. Findings suggested that carers were more sensitive to the cognitive limitations of the person and adapted their instructions accordingly to meet the person's cognitive needs during that task.

Whenever people with dementia contributed to problem-solving tasks, carers tended to provide cognitive support and gave positive feedback to motivate their relatives. Cognitive support strategies, therefore, could improve cognitive performance in the person with dementia and enhance their competence to accomplish their goals and may improve the quality of the caregiving relationship (Cavanaugh et al., 1989).

Cavanaugh and colleagues (1989) also found a second potential benefit of the carer cognitive support system. Sharing of cognitive tasks among people with dementia and their carer provided a positive environment that enhanced the quality of the caregiving relationship. For example, when carers interacted with their relative, they were more likely to adopt a positive attitude towards the person with dementia and identify their cognitive needs, which led to better cognitive support.

2.3 Conclusion

In dementia care, dyadic interpersonal interactions play a major role in the caregiving stress process. Evidence and theories suggest that dyadic interpersonal interactions such as positive (closeness) and negative (conflict) relationships (Townsend et al., 1995), mutual understanding, sharing pleasurable activities and meaningful experiences (Cartwright 1994) and cognitive support (Cavanagh 1989) may influence carer wellbeing. However, no theoretical model has adapted and conceptualised these theories in relation to carer involvement in CBIs for people with dementia on carer wellbeing.

In the theoretical framework of carer Involvement in CBIs for People with Dementia (Figure 2.3) the binding ties theory emphasises the importance of considering not only cognitive impairment in the person with dementia but also both positive and negative interpersonal ties in the caregiving relationship. An existing positive

relationship helps carers to adapt to the changing needs of the person with dementia and may protect them from experiencing negative consequences associated with the caring role. Therefore, when carers fail to adapt to these changes, it may lead to further negative effects on the caregiving relationship. In addition, negative ties are more strongly related to wellbeing than positive ties.

The enrichment processes involve mutual understanding, sharing pleasurable activities and meaningful experiences and provide a setting for maintaining or strengthening the dyadic relationship. As a result, the enrichment process enhances wellbeing for both carers and people with dementia. However, Cartwright and colleagues (1994) emphasise that the enrichment process only occurs either within the context of an existing positive relationship or being motivated to improve the relationship. Fine tuning is a core element of the enrichment process which is based on the theory of selection and optimisation compensation (Baltes 1997) and may be used to assist families in identifying strategies to engage in enriching activities (Cartwright et al., 1994). The scaffolding process therefore provides opportunities for carers to interact with the person with dementia and cognitively support them. Evidence indicates that cognitive support may enhance competence in achieving goals in the person with dementia and improve the caregiving relationship and carer wellbeing (Cavanaugh et al., 1989).

This theoretical framework is derived from the SPM of Pearlin (1990) that makes hypotheses on the effects of carer wellbeing in the context of carer involvement in CBIs for people with dementia. The proposed theoretical framework may broaden our understanding of interpersonal interactions, mutual sharing of pleasurable and meaningful activities and cognitive support by carers and their effects on carer

wellbeing. It also highlights that the key components of dyadic interpersonal interactions are interrelated and may act as mediators on carer wellbeing.

3 Chapter 3 The effects of carer involvement in CBIs for people with dementia on carer wellbeing: a systematic review and meta-analysis

3.1 Background

A systematic review suggests that carer involvement in psychosocial interventions can increase mutual understanding, enhance the quality of the caregiving relationship, improve the cognitive function of the person with dementia and enhance carer wellbeing (Moon & Adams, 2013). The study by Logsdon and colleagues (2007) evaluated the effects of early-stage support groups for people with dementia and their carers and showed that family conflict after participating in the support group significantly decreased compared to the control group. Carers in the control group reported increased family conflict in comparison to carers in the intervention group which reported their family conflicts remaining unchanged. Carer involvement therefore in psychosocial interventions can be associated with positive relationship functioning outcomes.

There is growing evidence of the benefits of psychosocial interventions for people with dementia on cognition and QoL (Moon & Adams 2013; Woods et al., 2012). Psychosocial interventions such as cognition-based interventions (CBIs) have been developed to improve cognition, enhance quality of life (QoL) and maximise engagement in activity and social participation for people with dementia (Bahar-Fuchs, Clare, & Woods, 2013; Woods et al., 2012). CBIs have been categorised into three types, which includes cognitive stimulation (CS), cognitive rehabilitation (CR) and cognitive training (CT) (Clare et al., 2004). A recent review showed that both people with dementia and their carers benefitted from psychosocial dyadic interventions, particularly in terms of improved cognitive function for the person with dementia and enhanced the caregiving relationship (Moon & Adams 2013). However, the inclusion of carers in CBIs has been reported as challenging in some

studies because carers may report increased depressive symptoms and burden when they participate in CBIs (Zarit, Zarit, & Reever, 1982; Milders, Bell, Lorimer, MacEwan, & McBain, 2013). However, there has been limited research in examining the effects of carer involvement in CBIs for people with dementia on carer wellbeing. I therefore conducted a systematic review to investigate the effects of carer involvement in CBIs for people with dementia on carer wellbeing.

3.2 Aim

To investigate the effects of carer involvement in CBIs for people with dementia on carer wellbeing.

3.3 Methods

Criteria for considering studies for this review

3.3.1 Types of studies

- Studies in which carers were involved in a CBI for the person with dementia
- Randomised controlled trials that provided adequate information in terms of results and description of the study (i.e. means, standard deviations (SDs), t-test or F-test, p and n-values)
- On-going trials were included if data were available and could be provided by authors

3.3.2 Types of participants

- Carers of people with dementia; the main diagnostic categories for people with dementia included Alzheimer's disease, vascular dementia or mixed Alzheimer's and vascular dementia
- Any setting (e.g. community, day centre or care home)

3.3.3 Types of interventions

For the purposes of this review, CBIs were defined as interventions that used Cognitive Stimulation (CS), Cognitive Rehabilitation (CR) and Cognitive Training (CT) approaches (Clare & Woods, 2004). CS provides a range of activities and opportunities for discussion that aim to engage the individual in general stimulation of memory and enhance social function, usually conducted in a group setting (Clare & Woods, 2004; Woods & Aguirre et al., 2012). CR is an individualised approach that focuses on reducing functional disability in people with dementia and maximising their engagement in everyday activities by identifying meaningful goals and developing strategies to address these goals (Clare et al., 2010). CT aims to maintain or improve cognitive function in people with dementia by using repeated and guided practice via a set of standardised tasks. These tasks target specific areas of cognitive function such as attention, memory, learning, executive function, language, perceptual-motor skills or social cognition (Sitzer, Twamley, & Jeste, 2006).

Studies were included if comparison conditions included 'no treatment', 'usual care' or 'treatment as usual'. 'Usual care' or 'treatment as usual' stands for a treatment normally provided to the person with dementia such as medication, clinic consultations, day care or other types of support. Usual care could consist, for example, of an equivalent number of sessions in which general support, but no structured intervention was offered to the person with dementia.

Multicomponent interventions were considered as eligible as long as the intervention was based on a CBI for people with dementia and involved carers.

3.3.4 Types of outcome measures

- Primary outcomes: carer wellbeing (including QoL, mood, physical and mental health)
- Secondary outcomes: caregiving relationship and carer burden

3.4 Search methods and identification of studies

Electronic databases and key articles were searched for randomised controlled trials (RCTs) published up to the 18th of December 2015 inclusive. The search was carried out in MEDLINE, Embase, Pubmed, PsycINFO, Alois (www.medicine.ox.ac.uk/alois), Cumulative Index of Nursing and Allied Health Literature (CINAHL) and the Cochrane Library.

Search terms included people with dementia, dementia, dementia*, Alzheimer*, "Alzheimer's disease", cognitive impairment, cognitive stimulation, cognitive rehabilitation, cognitive training, cognitive retraining, cognitive support, memory rehabilitation, memory therapy, memory aid, memory group, memory training, memory retraining, memory support, memory stimulation, memory strategy, reality orientation, rehabilitation training and cognitive psychostimulation, carer, caregiver*, randomised controlled trial, random*.

3.4.1 Data extraction and management

Two reviewers (PL and VO) extracted data independently by using a standardised data extraction form. Differences in the quality ratings of the papers were resolved by the third reviewer (MO) to reach a consensus. The information included data on methods, participants, type of intervention, model of delivery, outcome and results. Study authors were contacted for data not provided in the papers.

3.4.2 Quality assessment of included studies

The Cochrane Bias tool (Cochrane Handbook for Systematic Reviews of Interventions) was used to assess risk of bias. This tool reports and addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other issues.

3.5 Analyses

Calculation of effect sizes: Effect size Hedges' g (Hedges & Vevea, 1998) of continuous data was calculated as the standardised mean difference (SMD) with 95% confidence intervals (CIs) between the intervention and control groups. When means and standard deviations were not available, effect sizes were computed from exact p -values, t values or F values (Comprehensive Meta-analysis, Software-Version 2). The random effect model was used to decide whether an effect size was statistically significant (Hedges and Vevea, 1998). The weighted average effect size was calculated by the inverse of its variance (Revman 5).

3.6 Results of the search

3.6.1 Selection of studies

A total of 4721 studies were identified through database searching which was conducted from the period of July to December 2015. A total of 16 additional studies were identified via other sources. After removal of duplicates and irrelevant studies by title, 302 studies remained to be screened. A total of 257 studies were discarded as not relevant, and 45 studies remained for further screening. Nine of these studies were retrieved via full text, and 36 were excluded. Reasons for exclusion can be seen in Table 3.1. A total of 23 RCTs and one ongoing RCT did not report carer outcomes and carers were not involved in the intervention. Three RCTs did not involve carers in the interventions, but carer outcomes were examined. Two RCTs

reported carer involvement, but carer outcomes were not examined. The remaining seven studies did not employ an RCT, but carers were involved in the intervention. Four of these studies assessed carer outcomes. Amongst the nine included studies, one was an ongoing RCT (data not available). In the remaining eight included studies, only seven studies were included in the meta-analysis as for one of the studies data were not available. Figure 3.1 shows the PRISMA flow diagram detailing the search process.

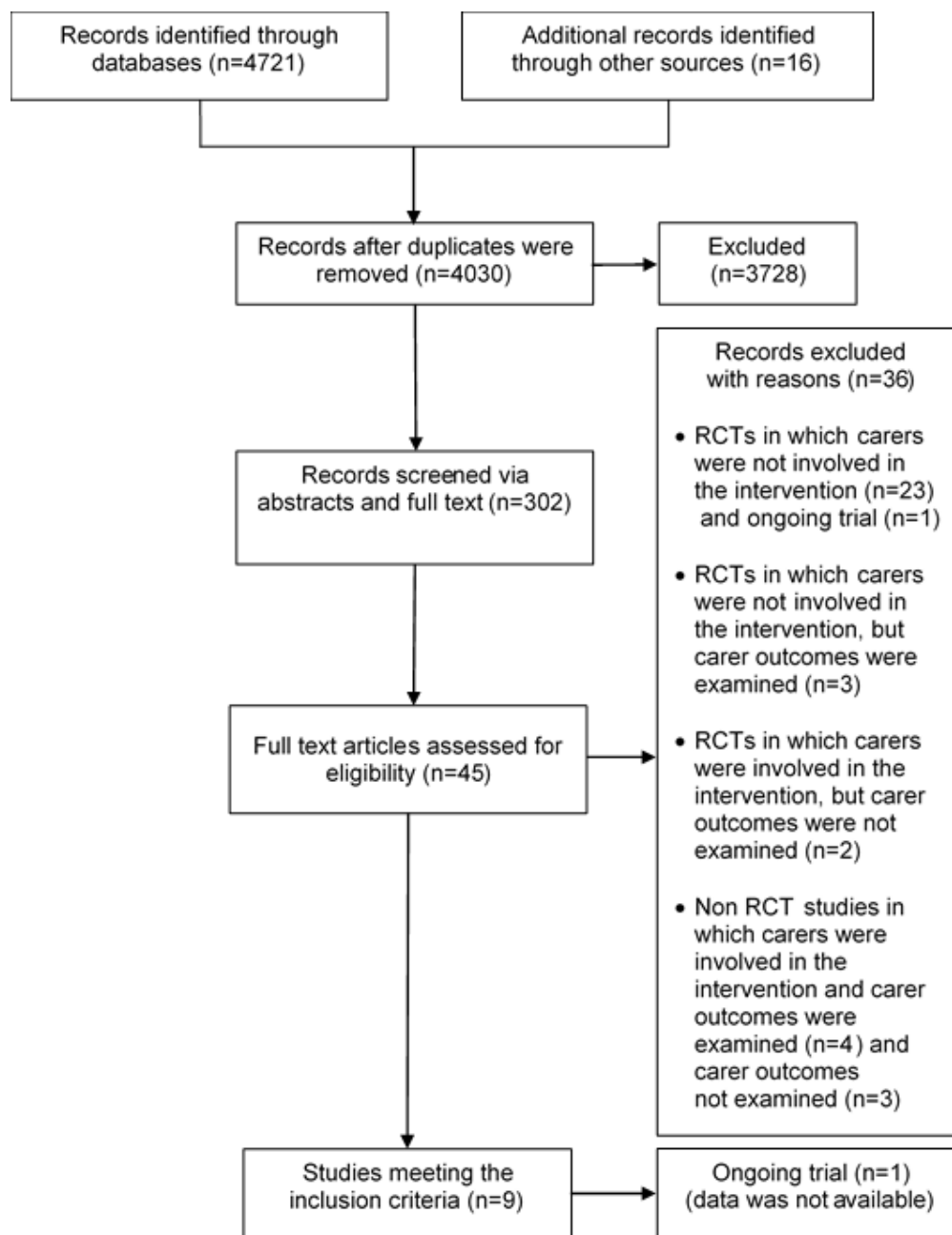


Figure 3.1 The PRISMA flow diagram detailing the search process.

Table 3.1 The characteristics of excluded studies

Reasons for exclusion		
Carers were not involved in the intervention and carer outcomes were not examined		
1. Andersen et al., 2012	RCT	Multi-component CBI
2. Baines et al., 1987	RCT	CS
3. Baldelli et al., 1993	RCT	CS
4. Baldelli et al., 2002	RCT	CS
5. Beck et al., 1988	RCT	CT
6. Breuil et al., 1994	RCT	CS
7. Cahn-Weiner et al., 2003	RCT	CT
8. Coen et al., 2011	RCT	CS
9. Cove et al., 2014	RCT	CS
10. de Vreese 1998	RCT	CT
11. Dwolatzky 2011	Ongoing RCT	CT
12. Ferrario et al., 1991	RCT	CS
13. Galante et al., 2007	RCT	CT
14. Graessel et al., 2011	RCT	Multi-component CBI
15. Heiss et al., 1993	RCT	CT
16. Koltai et al., 2001	RCT	CT
17. Lee et al., 2013	RCT	CT
18. Loewenstein et al., 2004	RCT	CT
19. Luttenberger et al., 2012	RCT	Multi-component CBI
20. Mapelli et al., 2013	RCT	CS
21. Requena et al., 2006	RCT	CS
22. Spector et al., 2003	RCT	CS
23. Wallis, et al., 1983	RCT	CS
24. Woods 1979	RCT	CS

Carers were involved in the intervention and carer outcomes were not examined		
1. Davis et al., 2001	RCT	CT
2. Quayhagen et al., 1995	RCT	CT
Carers were not involved in the intervention but carer outcomes were examined		
1. Aguirre et al., 2014	RCT	CS
2. Chapman et al., 2004	RCT	CS
3. Spector et al., 2001	RCT	CS
Carers were involved in the intervention and carer outcomes were examined (non RCTs)		
1. Clare et al., 2000	Non RCT	CR
2. Milders et al., 2013	Non RCT	CS
3. Moniz-Cook et al., 1998	Non RCT	CS
4. Viola et al., 2011	Non RCT	Multi-component CBI
Carers were involved in the intervention but carer outcomes were not examined (Non RCTs)		
1. Kesslak, Nackoul, & Sandman, 1997	Non RCT	CT
2. McKittrick, Camp, & Black, 1992	Non RCT	CT
3. Moore et al., 2001	Non RCT	CT
Carers were involved in the intervention and carer outcomes were examined		
1. Clare et al., 2013	Ongoing RCT	CR

3.6.2 Participants and types of CBIs

Eight studies were included in this review which were categorised into three main groups in accordance to level of carer involvement in the CBI (Figure 3.2).

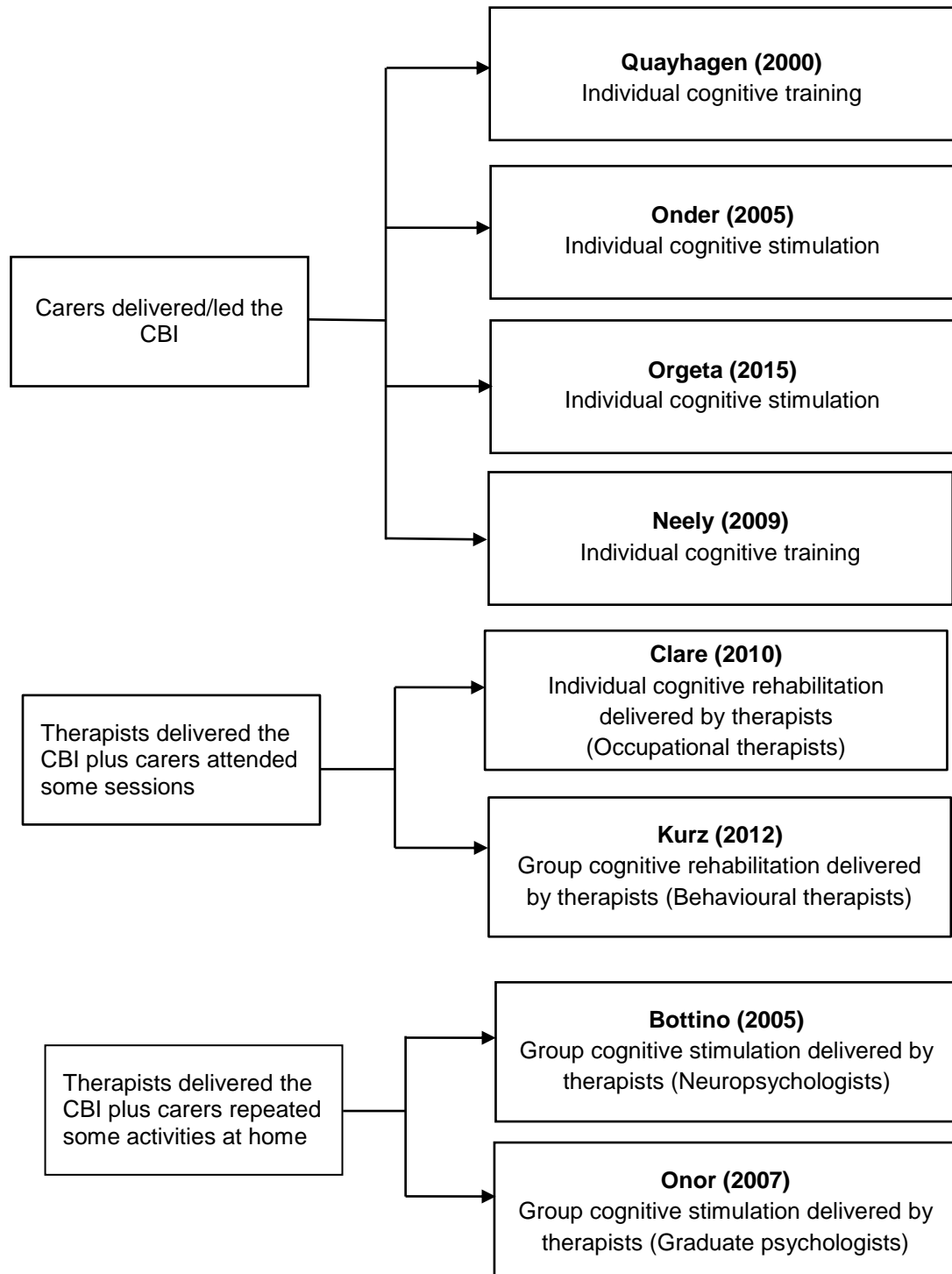


Figure 3.2 Level of carer involvement in the CBIs

3.6.2.1 Carers delivered/led the CBI

Study 1 (CT): Quayhagen et al., (2000) recruited 103 caregiving dyads living in the community in the USA. All the participants had a diagnosis of possible/probable AD, cardiovascular dementia or Parkinson's disease dementia and were in the mild or moderate stages of dementia with a Mattis Dementia Rating Scale (MDRS) (Mattis 1988) of 100 or above. The participants had a mean age of 74.5 years. Carers participating in the study had a mean age of 71.8 years. All carers were spouses of the person with dementia. People with dementia and carers were randomised to one of the four treatment groups which included CT (n = 21), dyadic counselling (n = 29), dual supportive seminar groups (n = 22), early-stage day care (n = 16) and wait-list control (n = 15). For this review, CT and wait-list control conditions were compared (Table 3.2). The individual home-based CT intervention comprised of cognitive stimulation (i.e. verbal and visual recall and recognition), problem-solving skills and conversation fluency activities. The participants received the intervention five times a week for 8 weeks, and each session lasted for 60 minutes. Carers were trained to deliver the intervention. They were instructed to provide cognitive support to the person with dementia by using their problem-solving techniques, cognitive stimulating and conversational fluency activities.

Study 2 (CS): Onder et al., (2005) included 156 participants living in the community in Italy. All participants were diagnosed with dementia using NINCDS-ADRDA criteria and had been on a stable dose of Donepezil for ≥ 3 months. The participants had a mean age of 75.7 years, and a mean MMSE score of 20. A total of 156 carers enrolled in the trial with an average age of 56.8 years. The relationship between carers and people with dementia was not reported. The study evaluated a home-based, individual RO intervention, which consisted of CS activities such as discussion of current affairs, information and topics of general interest such as

historical events, famous people, attention, and memory exercises. The intervention consisted of 30-minute sessions, for 3 times a week, over 25 weeks (Table 3.2). Carers were provided with a manual of instruction on the reality orientation therapy and were trained to deliver the sessions. They were invited to stimulate and involve the person with dementia in the reality-based communication activities.

Study 3 (CT): Neely et al., (2009) recruited 30 people living in the community who had a diagnosis of mild to moderate AD or vascular dementia (using DSM-IV criteria). The participants had a mean age of 75.4 years. Participants' mean MMSE score was 19.8. Thirty carers were involved in the study with a mean age of 73.8 years. The relationship between the person with dementia and their carer was not reported, and the study was conducted in Sweden. People with dementia and their carers were randomly assigned to either the collaborative individual CT intervention (n=10), the individual CT intervention with no carer involvement (n=10) or to the control group (n=10). For this review, the collaborative CT intervention and the control group were compared (Table 3.2). The individual home-based collaborative cognitive intervention consisted of face-name learning tasks and a table-setting activity. Spaced retrieval and provision of letter cues were used to support training on the face-name learning task, whereas a hierarchical cueing technique was used to support the table setting activity. The CT intervention consisted of 60-minute sessions weekly for 8 weeks (Table 3.2). Carers were trained to deliver the intervention. They were encouraged to apply practised and learning strategies to support their relative in the sessions.

Study 4 (CS): In the study by Orgeta et al., (2015) 356 dyads of people with dementia and their carers participated in the study. People with dementia met DSM-IV criteria for mild to moderate AD, mixed AD or vascular dementia with a mean age of 78.2

years. The mean MMSE score was 21.2. Of the 365 carers, 226 were spouses, and 113 were adult children, with the remaining being another relative or friend of the person with dementia. The study took place in the community in the UK. The individual cognitive stimulation therapy (iCST) intervention consisted of one-to-one, home-based structured CS activities, focusing on different themes such as current affairs, being creative, word games and music quizzes. People with dementia and carers were asked to complete up to 30-minute sessions, three times a week over 25 weeks (Table 3.2). Carers were provided with a manual of instruction of iCST and were trained to deliver the sessions. Carers participating in the sessions engaged the person with dementia in mentally stimulating activities.

3.6.2.2 Therapist delivered CBIs plus carers attending some sessions

Study 1 (CR): In the study by Clare et al., (2010) 69 participants in the community enrolled in the trial with a mean age of 77.8 years. All the participants were diagnosed with AD or mixed AD and vascular dementia (using NINCDS-ADRDA criteria). The mean MMSE score was 23.0. All participants were on a stable dose of acetylcholinesterase inhibitors (AChEIs). Forty-four carers were involved in the study with a mean age of 70.0 years. Of the 44 carers, 32 were spouses, 9 were adult children, and 3 were other relatives. The study was conducted in the UK. Of the 69 dyads randomised, 23 people with dementia and 16 of the carers were allocated to the CR intervention, 24 people with dementia and 9 carers to the individual relaxation therapy group and 22 people with dementia and 9 carers to the no-treatment control group. For this review, the individual CR intervention and the no-treatment control groups were compared (Table 3.2). The CR intervention included learning new information by using face-name learning tasks and practising maintaining attention and concentration. Additional elements were techniques for stress management. The CR intervention consisted of 60-minute sessions, once

weekly over eight weeks. Occupational therapists delivered the intervention. Carers were invited to join the last 15 minutes of each training session to support between-session implementation.

Study 2 (CR): Kurz and colleagues (2012) conducted the study in Germany and recruited 201 participants living in the community with a mean age of 73.7 years. All participants were diagnosed with AD based on the ICD-10 criteria with a mean MMSE score of 25. The study included 201 carers with a mean age of 64.9 years. Of the 201 carers, 72% were spouses and 28% were other relatives. The intervention was carried out in a multicenter setting of five university outpatient units. The intervention used external memory aids (i.e. calendar and communication skills aids) to establish behavioural routines to cope with memory problems. Additional elements included reminiscence and daily activity planning. People with dementia received 60-minute sessions, once a week for 12 weeks (Table 3.2). The intervention was delivered by behavioural therapists. Carers attended one in every two sessions during the 12-week intervention period. Carers were trained and encouraged to apply 'the transfer of newly learned strategies into everyday life' when communicating about memories with the person with dementia.

3.6.2.3 Therapist delivered CBI plus carers repeating some activities at home

Study 1 (CS): Bottino et al., (2005) enrolled 13 people with dementia living in the community with a mean age of 73.3 years. All participants met NINCDS-ADRDA criteria for probable AD and had a stable dose of 6-12 mg/a day of Rivastigmine for ≥ 2 months. The mean MMSE score was 22.3. Thirteen carers enrolled in the study. Carers' average age and their relationship to the person with dementia were not provided. The study was conducted in Brazil. The study evaluated the effects of a group CS intervention combined with AChEIs. The intervention included orientation

activities, discussion of themes, reminiscence activities, making associations between objects and planning of daily activities using calendars, clocks or other external memory aids. The intervention consisted of 90-minute sessions, once a week for 20 weeks. Neuropsychologists delivered the intervention (Table 3.2). Carers were trained to repeat some activities between the sessions at home at least three times a week.

Study 2 (CS): Onor (2007) included 16 participants with a diagnosis of mild to moderate AD accordance to DSM-IV and NINCDS-ADRDA criteria with a mean MMSE score of 22.4. All participants lived in the community with a mean age of 70.0 years. Sixteen carers took part in the study. Their age and relationship to the person with dementia was not specified. The study was conducted in Italy. In this study, the group CS intervention included RO of time, place and people. People with dementia attended 60-minute sessions, three times a week for 16 weeks. Psychologists delivered the intervention. Carers were trained to repeat some of the activities at home at various times of the day (Table 3.2)

Table 3.2 The characteristics of included studies

Study	Country	Sample		Intervention group	Control group	Carer outcomes
		People with dementia	Carers			
Quayhagen (2000)	USA	n = 36 Mean age: 74.5 Inclusion criteria: - Diagnosis of Alzheimer's disease or/and cardiovascular dementia and Parkinson's disease dementia - Mattis Dementia Rating Scale ≥ 100	n=36 Mean age: 71.8 Relation to person with dementia: Spousal carers	Individual CT: memory stimulation, problem solving and conversation fluency tasks. - Intensity: 60 -minute sessions - Frequency: 5 sessions weekly - Duration: 8 weeks - Carers were trained to deliver the intervention	People with dementia - Wait-list Carers - No treatment	QoL Life satisfaction (PGCMS) Mood Anxiety (BSI) Depression (BSI) Caregiving relationship Marital Needs Satisfaction (MNSS) Physical health Health Assessment (HAS)
Onder (2005)	Italy	n = 156 Mean age: 75.7 Mean MMSE: 20.0 Inclusion criteria: - Diagnosis of dementia (NINCDS-ADRDA) - MMSE (14-27) - Received donepezil for at least 3 months	n = 156 Mean age: 56.8 Relation to person with dementia: not provided	Individual CS: space orientation tasks, historical events, famous people and exercises of memory, visuospatial orientation and communication - Intensity: 30-minute sessions - Frequency: 3 sessions weekly - Duration: 25 weeks - Carers were trained to deliver the intervention	People with dementia - Treatment as usual Carers - No treatment	QoL Health survey (SF-36) Mood Anxiety (HRSA) Depression (HRSD) Burden CBI burden (CBI)

Neely (2009)	Sweden	<p>n = 20</p> <p>Mean age: 75.4</p> <p>Mean MMSE: 19.8</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> - Diagnosis of dementia (DSM-IV) 	<p>Carers: n = 20</p> <p>Mean age: 73.8</p> <p>Relation to person with dementia: Not provided</p>	<p>Individual CT: practice strategies to support everyday mnemonic and occupational performance, cognitive training strategies of spaced retrieval and face name tasks</p> <ul style="list-style-type: none"> - Intensity: 60-minute sessions - Frequency: 1 session weekly - Duration: 8 weeks - Carers were trained to deliver the intervention 	<p>People with dementia</p> <ul style="list-style-type: none"> - Treatment as usual <p>Carers</p> <ul style="list-style-type: none"> - No treatment 	<p>Mood</p> <p>Depression (BDI)</p> <p>Burden</p> <p>Carer Burden (CBI)</p>
Orgeta (2015)	UK	<p>n = 356</p> <p>Mean age = 78.2</p> <p>Mean MMSE: 21.2</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> - Diagnosis of mild to moderate dementia (DSM-IV) - MMSE ≥ 10 	<p>n= 356</p> <p>Mean age: 65.7</p> <p>Relation to person with dementia:</p> <p>Spouses (63%), adult children & siblings (32%), Other relatives (5%)</p>	<p>Individual home-based CS therapy consisting of orientation activities and structured themes in each session (i.e. current affairs, words games, music quizzes)</p> <ul style="list-style-type: none"> - Intensity: 30-minute sessions - Frequency: 3 sessions weekly - Duration: 25 weeks - Carers were trained to deliver the intervention 	<p>People with dementia</p> <ul style="list-style-type: none"> - Treatment as usual <p>Carers</p> <ul style="list-style-type: none"> - No treatment 	<p>QoL</p> <p>Health survey (SF-12)</p> <p>Health-related QoL EQ-5D</p> <p>Relationship functioning</p> <p>Quality Carer/Patient Relationship (QCPR)</p> <p>Mood</p> <p>Anxiety (HADS-A)</p> <p>Depression (HADS-D)</p>
Clare (2010)	UK	<p>n = 45</p> <p>Mean age 77.8</p> <p>Mean MMSE: 23.0</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> - Diagnosis of dementia (NINCDS/ADRAD) - MMSE ≥ 18 	<p>n = 25</p> <p>Mean age: 70.0</p> <p>Relation to person with dementia:</p> <p>Spouses: (73%),</p>	<p>Individual CR: practical aids, strategies and techniques for learning new information, maintaining attention and concentration and techniques of stress management</p> <ul style="list-style-type: none"> - Intensity: 60-minute sessions - Frequency: 1 session weekly 	<p>People with dementia</p> <ul style="list-style-type: none"> - Usual care <p>Carers</p> <ul style="list-style-type: none"> - No treatment 	<p>QoL</p> <p>WHOQOL BREF QoL: 5 sub-scales.</p> <p>Mood</p> <p>Anxiety (HADS-A)</p> <p>Depression (HADS-D)</p> <p>Carer burden</p>

		- Taking AChEIs at least 4 weeks	adult children: (20%), Other relatives: (7%)	- Duration: 8 weeks - Occupational therapists delivered the intervention - Carers attended the last 15 minutes of each CR session if they were available		Relative's Stress (RSS) Mental health General Health (GHQ- 12)
Kurz (2012)	Germany	n = 201 Mean age: 73.7 MMSE: 25.1 Inclusion criteria: - Dementia diagnosis (ICD-10) - MMSE ≥ 21	N=201 Mean age: 64.9 Relation to person with dementia: Spouses: (72%), other relatives (28%)	Individual multi-component cognitive behaviour therapy (CBT) & CR programme of 6 modules (12 sessions), including use of external memory aids, coping with memory- related problems, reminiscence and activity planning. - Intensity: 60-minute sessions - Frequency: 1 session weekly - Duration: 12 weeks - Behavioural therapists delivered the intervention - Carers attended six sessions with the person with dementia	People with dementia - Usual care Carers - No treatment	Mood Depression (BDI) Burden Burden (ZBI)
Bottino (2005)	Brazil	n = 13 Mean age: 73.7 Mean MMSE: 22.3 Inclusion criteria: - Diagnosis of dementia (NINCDS-ADRDA) - Taking Rivastigmine for 2 months	n = 13 - Mean age: not provided - Relation to person with dementia: not provided	Group CS: orientation activities, discussion of themes, reminiscence and planning of daily activities via use of calendars and clocks or other external memory aids - Intensity: 90-minute sessions - Frequency: 1 session weekly - Duration: 20 weeks	People with dementia - Treatment as usual Carers - No treatment	Mood Anxiety (HAM-A) Depression (MADRS)

				<ul style="list-style-type: none"> - Neuropsychologists delivered the intervention - Carers were trained to repeat some activities at home in between the group sessions for at least three times a week 		
Onor (2007)	Italy	n = 16 Mean age: 70.0 Mean MMSE: 22.4 Inclusion criteria: <ul style="list-style-type: none"> - Mild-moderate dementia (DSM-IV and NINCDS/ADRAD) - Received AChEIs ≥ 6 months 	Carers: n=16 Mean age: Not provided - Relation to person with dementia: Not provided	CS group programme: RO therapy (memory events, people, objects, songs and rhymes) and implicit memory stimulation tasks (i.e. daily personal care and activities) through occupational therapy <ul style="list-style-type: none"> - Intensity: 60-minute sessions - Frequency: 3 sessions weekly - Duration: 16 weeks - Psychologists delivered the intervention - Carers were trained to repeat some activities at home at various times of the day 	People with dementia <ul style="list-style-type: none"> - Treatment as usual - No treatment 	Mood Anxiety (BSI) Depression (BSI) Burden Carer Burden (CBI)

PGCMS, Philadelphia Geriatric Center Morale scale; BSI, Brief Symptom Inventory (anxiety and depression); MNSS, Marital Needs Satisfaction Scale; HAS, Health Assessment Scale; SF-36, Health Survey Short Form; HRSA, Hamilton Rating Scale for Anxiety; HRSD, Hamilton Rating Scale for Depression; CBI, Carer Burden Inventory; BDI, Beck Depression Inventory; SF-12, Health Survey Short Form; EQ5-D VAS, Europe Quality of Life Visual Analogue Scale; QCPR, quality caregiver/patient relationship; HADS-A, Hospital Anxiety and Depression Scale; HADS-D, Hospital Anxiety and Depression Scale; WHOQOL-BREF, World Health Organisation Quality of Life Assessment Short Version; RSS, Relative's Stress Scale; GHQ-12, General Health Questionnaire; ZBI, Zarit Burden Interview; HAM-A, Hamilton Anxiety Scale; MADRS, Montgomery-Asberg Depression Rating Scale; BSI-A, Brief Symptom Inventory-Anxiety; BSI-D, Brief Symptom Inventory-Depression.

3.7 Carer outcome measures

3.7.1 Quality of Life

The study by Onder (2005) measured physical and mental health using the Medical Outcomes Study 36-item Short-Form Health Survey (SF36) (Ware & Sherbourne, 1992). Higher scores indicate better physical and mental health. Orgeta (2015) employed the short version of the questionnaire: the Short Form Health Survey Questionnaire-12 items (SF-12) (Ware Jr, Kosinski, & Keller, 1996), in which higher scores indicate better physical and mental health. Orgeta (2015) also measured health-related QoL by using the Health-related Quality of Life EQ-5D (Brooks, 1996). The EQ-5D provides a simple descriptive system of five dimensions of HR-QoL: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some problems, extreme problems. A single index is used to provide values for health status by using a Visual Analogue Scale (VAS) (EuroQoL, 2005). Clare (2010) measured carer QoL by using the 26-item scale short-version of the World Health Organization Quality of Life questionnaire (WHOQOL-BREF) (Skevington, Lotfy, & O'Connell, 2004). The WHOQOL-BREF includes physical, psychological, social and environmental domains with higher scores indicating better QoL. Quayhagen (2000) measured life satisfaction by using the Philadelphia Geriatric Center Morale Scale (PGCMS). The PGCMS is comprised of 17 questions, where higher scores indicate greater satisfaction with life (Lawton, 2001).

3.7.2 Anxiety/depression

Quayhagen (2000) and Onor (2007) employed the 53-item Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983) to measure carers' anxiety and depressive symptoms. The study by Onder (2005) employed the 21-items Hamilton Rating Scale for Anxiety to measure anxiety (HRSA) (Hamilton, 1959) and the Hamilton

Rating Scale for Depression (HRSD) (Hamilton, 1967) to measure depressive symptoms. Clare (2010) and Orgeta (2015) employed the Hospital Anxiety and Depression Scale (HADS-A and HAD-D) (Zigmond & Snaith, 1983) to measure anxiety and depressive symptoms. The HADS is comprised of 14 items, which are divided into two independent subscales with higher scores indicating greater severity of anxiety and depressive symptoms. In the study by Bottino (2005), the Montgomery-Asberg Depression Rating Scale (Montgomery 1979) was used to quantify depressive symptoms. In this scale, higher scores indicate more severe depressive symptoms. Bottino (2005) also used the Hamilton Anxiety Rating Scale (HAM-A) (Bruss, Gruenberg, Goldstein, & Barber, 1994) to assess anxiety symptoms. Scores of the HAM-A range from 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe symptoms. Neely (2009) and Kurz (2012) measured depressive symptoms using the Beck Depression Inventory (BDI) (Beck, Steer, & Brown, 1996). The BDI is a 21-item self-report questionnaire designed to measure the severity of depressive symptoms. Higher scores indicate greater severity of symptoms.

3.7.3 Physical health/Mental health

Quayhagen (2000) evaluated physical health status by using the 25-item Health Assessment Scale (Rosencranz & Pihlblad, 1970). A 5-point Likert-type scale is used which ranges from "good" to "poor", assessing the severity and frequency of health problems. Clare (2010) employed the General Health Questionnaire GHQ-28 (Goldberg 1992) to measure carers' mental health. Scores range from 0 to 28 with higher scores indicative of greater psychiatric distress.

3.7.4 Carer/patient relationship

Quayhagen (2000) assessed relationship functioning by using the 24-item Marital Needs Satisfaction Scale (MNSS) (Stinnett et al., 1970). The MNSS consists of six areas of marital needs, which are love, respect, communication, personality fulfilment, life meaningfulness and the integration of life experiences. Higher scores indicate greater satisfaction of marital needs. Orgeta (2015) measured the quality of the caregiving relationship by using the Quality of the Carer Patient Relationship (QCPR) scale (Spruytte, Van Audenhove, Lammertyn, & Storms, 2002). This measure comprises 14 items (5-point Likert-type scale), which range from "totally disagree" to "totally agree". The scale measures the warmth of the relationship and the absence of conflict and criticism. The items on the criticism and conflict subscales are reverse coded so that higher scores reflect better relationship quality.

3.7.5 Carer burden/relative stress

Quayhagen (2000) measured carer hostility by using the subscale of the 53-item Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983) with higher scores indicative of greater hostility. Onder (2005), Onor (2007) and Neely (2009) used the Carer Burden Inventory (CBI) (Novak & Guest, 1989) to measure carer burden. The CBI consists of 24 items, which are categorised into five sections: objective burden, developmental burden, physical burden, social burden and emotional burden. The scores range from 0 to 96, where higher scores indicate greater levels of burden. The study by Kurz (2012) employed the Zarit Burden Interview (ZBI) (Zarit, Reever, & Bach-Peterson, 1980) to rate carer burden. This scale consists of 22 items and covers psychological, emotional, social, financial and health problems using a 5-point Likert-type scale (0 =never, 4 =always). The ZBI ranges between 0-88 with higher scores indicating greater perceived carer burden. Clare (2010) employed the Relative's Stress Scale (RSS) (Greene, Smith, Gardiner, & Timbury, 1982) to

evaluate carer stress. The RSS covers various aspects of stress such as emotional distress, social distress and negative feelings. It consists of 15 items with higher scores indicative of greater distress.

3.8 Quality assessment of included studies

The Cochrane Risk of Bias Tool (Cochrane Handbook for Systematic Reviews of Interventions) (Higgins and Green, 2008) was used to assess risk of bias in included studies. This addresses six specific domains: (i) sequence generation, (ii) allocation concealment, (iii) blinding, (iv) incomplete outcome data, (v) selective reporting and (vi) other issues. Each of these domains was rated as a 'low risk', 'high risk' or 'unclear risk' of bias. The review authors worked independently in relation to input of entries in a risk of bias table. Differences of judgement of risk of bias were resolved by discussion or by involving the third author (MO). Table 3.3 presents the summarised results for "Risk of bias" assessment of included studies.

3.8.1 Sequence generation

The studies of Onder (2005), Orgeta (2015), Clare (2010), Kurz (2012) and Bottino (2005) specified how random sequence generation was generated. The study by Quayhagen (2000), Neely (2009) and Onor (2007) did not provide details of sequence generation. Therefore, these studies were classified as having unclear bias in this domain.

3.8.2 Allocation concealment

All studies reported the use of randomisation. However, descriptions and details by individual studies varied. Five studies provided adequate descriptions of allocation concealment (Onder 2005, Orgeta 2015, Clare 2010, Kurz 2012 and Bottino 2005). These studies were classified as low risk of bias in this domain. Quayhagen (2000),

Neely (2009) and Onor (2007) did not describe any details of allocation; therefore, these studies were identified as having an unclear risk of bias in this domain.

3.8.3 Blinding

The studies by Quayhagen (2000), Onder (2005), Orgeta (2015), Clare (2010), Kurz (2012) and Bottino (2005) reported the assessors being blind to outcome assessments. Therefore, these studies were classified as being at low risk of bias. Neely (2009) and Onor (2007) did not report details of blinding assessment; therefore, these studies were classified as being of unclear risk.

3.8.4 Incomplete outcome data

Onder (2005), Orgeta (2015), Clare (2010), Kurz (2012) and Onor (2007) reported attrition for both treatment and control groups. They were therefore classified as low risk. Quayhagen (2000), Neely (2009) and Bottino (2005) were judged as having unclear risk in this domain because they did not provide attrition details.

3.8.5 Selective reporting

All studies reported all pre-specified outcomes and were classified as low risk of bias in this domain

3.8.6 Other potential sources of bias

No additional risk of biases was identified in each of the included studies.

Table 3.3 Risk of bias of included studies

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other issues
Carers delivered/led CBIs						
Quayhagen (2000)	No details of sequence generation	No details of method of concealment	Assessors were blind to outcome assessments	No report of attrition	All outcomes reported	No issues identified
Author's judgement	Unclear	Unclear	Low risk	Unclear	Low risk	Low risk
Onder (2005)	Randomisation performed by computer	Group allocation was concealed from blind assessors	Assessors were blind to outcome assessments	Attrition data reported: 9 (13%) in the treatment group, 10 (15%) in the control group	All outcomes reported	No issues identified
Author's judgement	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Neely (2009)	No details of randomisation Insufficient information about sequence generation	No details of method of concealment	No details of blinding assessment	Unclear details of missing data for one dyad in the control group	All pre-specified outcomes reported	No issues identified
Author's judgement	Unclear	Unclear	Unclear	Unclear	Low risk	Low risk
Orgeta (2015)	Computer-generated randomisation by an independent trials unit using a computer algorithm	Group allocation was concealed from blind assessors	Assessors were blind to outcome assessments	Attrition data reported: 46 (26%) in the treatment group and 37 (21%) in the control group	All outcomes reported	No issues identified
Author's judgement	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk

Therapists delivered CBIs and carers attended some sessions						
Clare (2010)	Randomisation was conducted by an independent trials unit using a computer algorithm	Group allocation was concealed from blind assessors	Assessors were blind to outcome assessments	Attrition data reported: 7 (30%) in the treatment group and 2 (9%) in the control group	All pre-specified outcomes reported	No issues identified
Author's judgement	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Kurz (2012)	Computer-generated randomisation	Group allocation was concealed from blind assessors	Assessors were blind to outcome assessments	Attrition data reported: 9 (9%) in the treatment group and 9 (8.9%) in the control group	All pre-specified outcomes reported	No issues identified
Author's judgement	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Therapists delivered CBIs and carers repeated some activities at home						
Bottino (2005)	Randomised blocks design	Randomised blocks design in two groups	Assessors were blind to outcome assessments	No attrition reported	All pre-specified outcomes reported	No issues identified
Author's judgement	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk
Onor (2007)	No details of randomisation provided	No details of method of concealment was provided	No details of blinding assessment	None of the participants dropped-out from the trial	All pre-specified outcomes reported	No issues identified
Author's judgement	Unclear	Unclear	Unclear	Low risk	Low risk	Low risk

3.9 Results

This review investigated the effects of carer involvement in CBIs for people with dementia on carer wellbeing. Eight RCTs met the inclusion criteria. Across studies people were diagnosed with mild to moderate dementia. The studies were categorised into three groups in accordance to level of carer involvement in CBIs, which included: a) carers delivering/leading the CBI; b) carers attending some sessions and therapists delivering the CBI; and c) therapists delivering the CBIs plus carers repeating some activities at home. The duration of these studies ranged from 8 to 25 weeks with frequencies of provision of the intervention ranging from 3 to 5 sessions weekly. The duration of each session varied from 30 to 90 minutes. A total of 803 carers of people with dementia were included in the meta-analysis. The study by Neely (2009) was not included in this meta-analysis, because data were not available.

3.9.1 Carer quality of Life

Three studies assessed carer QoL. This outcome was measured by the Philadelphia Geriatric Center Morale Scales (PGCMS); the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) and the EQ-5D (Quayhagen 2000; Onder 2005; Orgeta 2015). Three studies were included in the meta-analysis and significant differences were found between the intervention and control groups. The effect size was Hedges' $g = 0.22$; 95% CI of 0.02 - 0.42, $z = 2.19$ and $p = 0.03$, indicative of a small effect. The heterogeneity between studies was $I^2 = 9\%$ (Figure 3.3). The data of Health Survey SF-12 (Ware et al., 1996) in the study by Orgeta et al., (2015) and the WHOQOL-BREF Questionnaires in the study by Clare et al., (2010) cannot be pooled in the meta-analysis because only the sub-scale scores of these measures were reported.

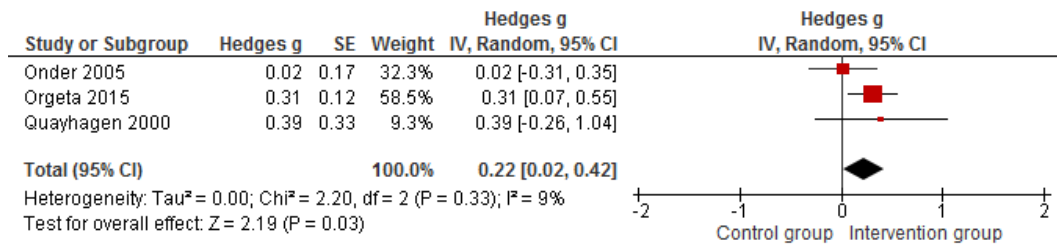


Figure 3.3 Forest plot of carer quality of life

Carer involvement in CBIs for people with dementia vs no CBIs at follow-up for carer QoL

3.9.2 Carer anxiety/depressive symptoms

Six studies examined anxiety (Quayhagen 2000; Onder 2005; Orgeta 2015; Clare 2010; Bottino 2005; Onor 2007). Meta-analysis showed no evidence of a significant effect for anxiety symptoms for carers in the treatment group vs the control group, Hedges' $g = 0.08$; 95% CI of -0.09 - 0.26, $z = 0.92$, and $p = 0.36$. There was no heterogeneity between studies $I^2=0\%$ (Figure 3.4).

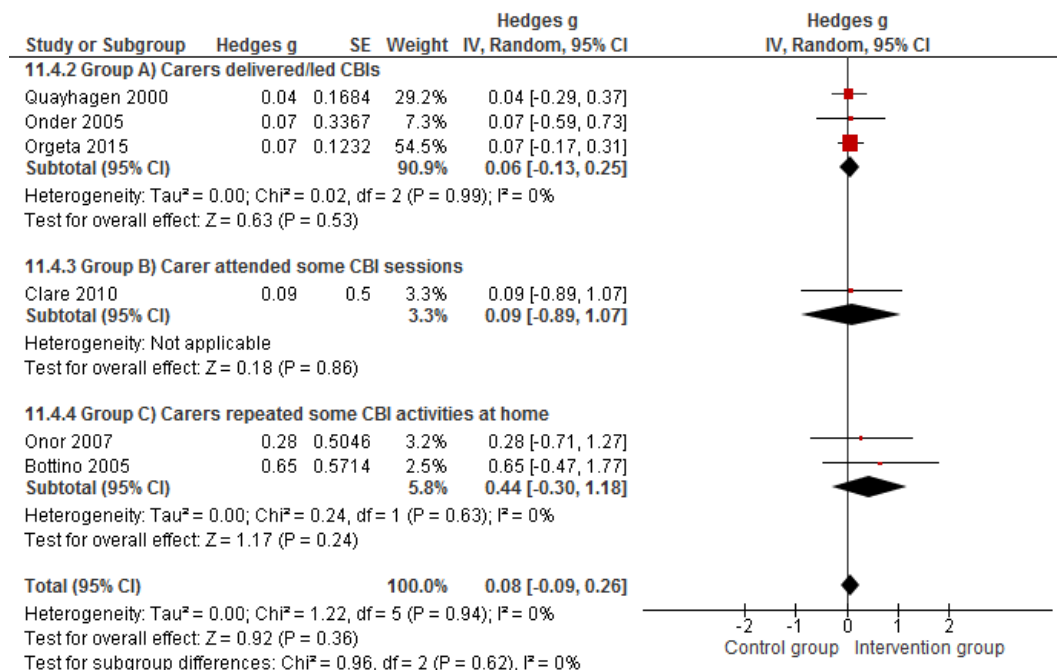


Figure 3.4 Forest plot of carer anxiety symptoms

Carer involvement in CBIs for people with dementia vs no CBIs at follow-up for carer anxiety symptoms

Seven studies assessed carers' depressive symptoms. A meta-analysis showed a significant effect favouring the intervention group with Hedges' $g = 0.17$; 95% CI of 0.02 - 0.32, $z=2.19$ and $p=0.03$ indicative of a small effect. There was no heterogeneity between studies $I^2=0\%$ (Figure 3.5). The study by Neely (2009) was not included in this meta-analysis, due to data not being available.

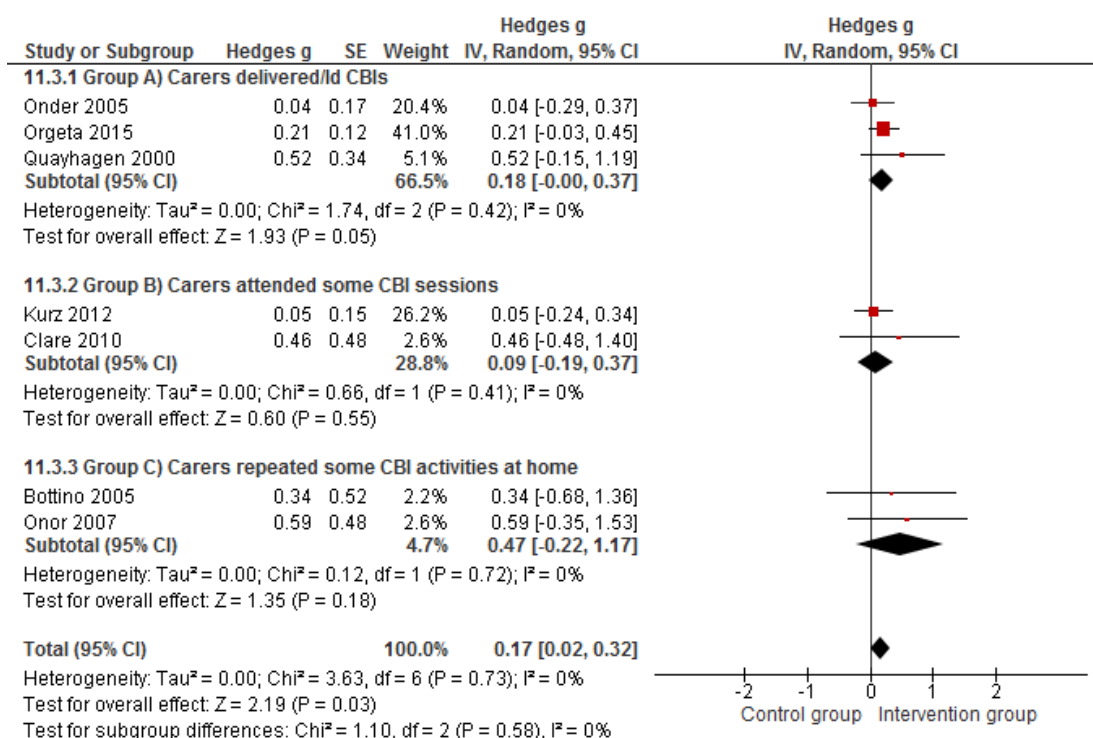


Figure 3.5 Forest plot of carer depressive symptoms

Carer involvement in CBIs for people with dementia vs no CBIs at follow-up for carer depressive symptoms

3.9.3 Carer physical health

Two studies evaluated physical health (Quayhagen 2000; Orgeta 2015) and two studies mental health (Orgeta 2015; Clare 2010) by using the Health Assessment Scale, and the Short Form Health Survey Questionnaire-12 items (SF-12) (comprising the Physical Component Summary (PCS) and the Mental Component Summary (MCS) and the General Health Questionnaire GHQ-28, respectively. The

data for these outcomes could not be pooled for meta-analysis as the outcome measures are different.

3.9.4 The carer/patient relationship

The Marital Needs Satisfaction Scale (MNSS) and the Quality of the Carer Patient Relationship (QCPR) were used to evaluate relationship functioning between carers and people with dementia (Quayhagen 2000; Orgeta 2015), assessed by two studies. Meta-analysis showed no significant effect on relationship functioning of carer-delivered CBIs, Hedges' $g = 0.01$; 90% CI of $-0.23 - 0.24$, $z = 0.05$ and $p = 0.96$. There was no heterogeneity between studies $I^2=0\%$ (Figure 3.6).

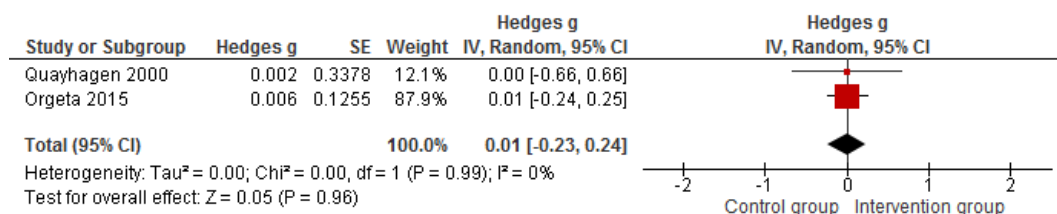


Figure 3.6 Forest plot of the carer/patient relationship

Carer involvement in CBIs for people with dementia vs no CBIs at follow-up for carer/patient relationship

3.9.5 Carer burden

Four studies measured levels of carer burden. Onder (2005) and Onor (2007) used the Carer Burden Inventory (CBI). The study by Kurz (2012) employed the Zarit Burden Interview (ZBI) and Clare (2010) employed the Relative's Stress Scale (RSS). No significant difference was found between treatment and control groups for carer burden. Meta-analysis indicated an effect size of Hedges' $g = -0.01$; 95% CI of $-0.34 - 0.33$, $z = 0.03$ and $p = 0.98$, for carer burden. The heterogeneity between studies was $I^2 = 31.8\%$ (Figure 3.7).

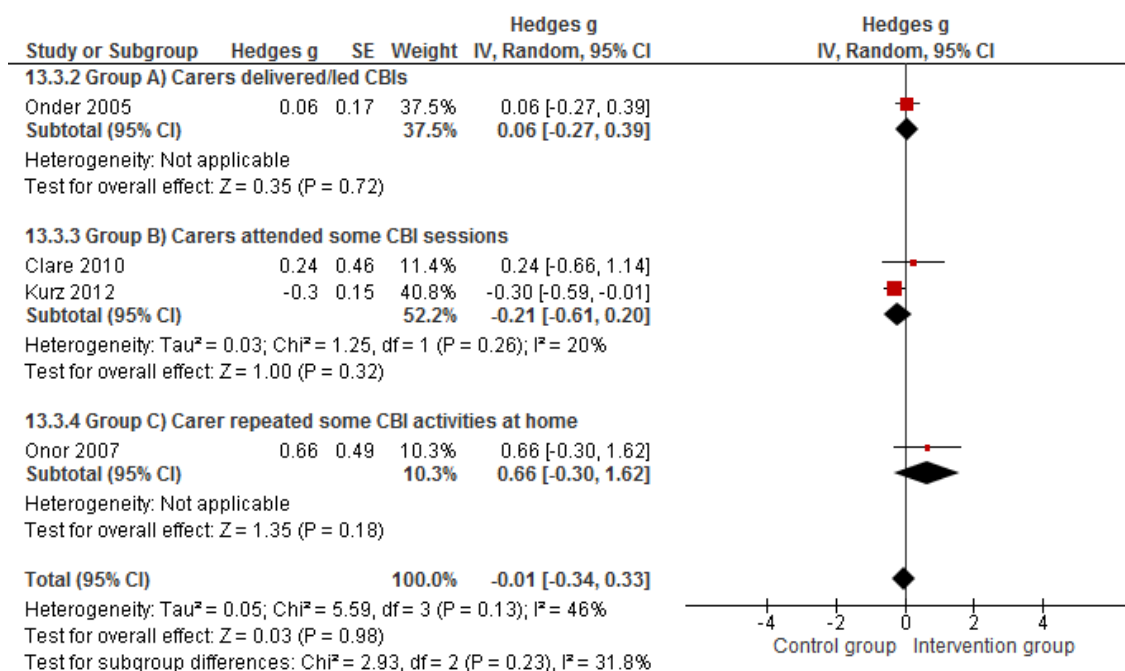


Figure 3.7 Forest plot of carer burden

Carer involvement in CBIs for people with dementia vs no CBIs at follow-up for carer burden

3.10 Discussion

To my knowledge, this is the first systematic review evaluating the effects of carer involvement in CBIs for people with dementia on carer wellbeing. The results indicate that carers' QoL and depressive symptoms may improve. Although the effect sizes are small, the findings are consistent with the theoretical predictions of the binding ties theories (Townsend & Frank 1995), enrichment process (Cartwright et al., 1994) and scaffolding process (Cavanaugh et al., 1989).

The findings of the meta-analyses indicate that carer involvement in CBIs has no effects on the caregiving. The meta-analyses also showed that carer involvement in CBIs had no effects on anxiety symptoms or carer burden. Clare (2010) found a small effect size of 0.25 on carer burden reduction for the intervention group, whereas Kurz (2012) found an effect size of 0.30 favouring the control group.

This review identified four non-RCTs that involved carers in the CBI and examined carer outcomes. Moniz-Cook and colleagues (1998) evaluated carer involvement in an individual home-based memory orientation programme, in which carers received psycho-education and counselling. The study found that carer wellbeing decreased in the control group. Clare (2000) conducted a multiple single case study to investigate the effects of errorless learning principles for people with dementia and their carers. There was no evidence of effects on carers' anxiety or depressive symptoms when carers were involved in the CBI activities. Viola et al. (2011) conducted a multicomponent CR for people with dementia which involved carers repeating some of the activities at home. Carers also received psychoeducation and counselling sessions. The study reported significant differences in depressive symptoms and carer burden for those involved in the sessions which reported less depressive symptoms and lower carer burden. In contrast, the study by Milders and colleagues (2013), which examined effects of a carer-delivered CS intervention found that carers in the intervention group reported higher levels of burden compared to the control group.

Amongst the 36 excluded studies, three RCTs reported carer outcomes, but carers were not involved in the intervention (Aguirre et al., 2014; Chapman et al., 2004; Spector et al., 2001). The study by Aguirre and colleagues (2014) examined the effects of group CST for people with dementia on carer QoL. The findings showed no evidence of improvement in carers' physical and mental health (SF-12) and HR-QoL (EQ-5D). Chapman and colleagues (2004) examined the effects of cognitive communication stimulation for people with dementia. This study however measured carers' distress by using the Neuropsychiatric Inventory (NPI) (Cummings et al., 1994), which is not a validated measure for carer distress (Lai 2014). The study by Spector (2001) described the development and implementation of group CS therapy

for people with dementia. The findings showed that caregiving stress (Relative's Stress (RS) Scale; Greene, Smith, Gardiner, & Timbury, 1982) increased both in the intervention group and the control group, however, carers in the intervention group reported an improvement however in general psychological distress (General Health Questionnaire 12 (GHQ-12); Goldberg, 1978). The data for these outcomes can't be pooled in a meta-analysis as the outcome measures used vary in term of what is being measured and underlying concepts.

A Cochrane review by Woods et al. (2012) examining the effects of CS on people with dementia identified three studies in which carer outcomes were examined. Two of these studies involved carers in the intervention (Bottino et al., 2005; Onder et al., 2005), but a study by Spector et al. (2001) did not. Their findings showed no significant differences in carer anxiety, depression, carer burden and general health. Another Cochrane review by Bahar- Fuchs et al., (2013) evaluating the effects of CT and CR on cognition for in people with dementia identified five studies in which carers were involved in the intervention. Of these, three studies examined carer outcomes (Clare et al., 2010; Neely et al., 2009; Quayhagen al., 2000), but two studies did not (Davis et al., 2001; Quayhagen et al., 1995). However, this Cochrane review did not statistically examine carer outcomes.

The current review evaluated the effects of carer involvement in CBIs on people with dementia on carer outcomes, specifically carer wellbeing. The iCST intervention is categorised as a CBI (Clare et al., 2004) and consists of one-to-one structured cognitive stimulation sessions for people with dementia that are delivered by carers at home. The iCST intervention is developed based on the evidence base of group CST which offers people with mild to moderate dementia opportunities to take part in a range of activities that are comprised by several themes of general cognitive

stimulation. These activities include current affairs, being creative, word games and quizzes which aim to improve cognition and QoL for people with dementia. iCST provides opportunities for the person with dementia and carers to interact, share pleasurable meaningful experiences and mentally stimulating activities. iCST can also be conceptualised as an intervention during which carers can provide cognitive support to the person with dementia, assist with problem solving and provide positive feedback.

Findings of the systematic review indicated that carer involvement in CBIs is associated with improvements in carer QOL and a reduction in depressive symptoms. These results support the theories of carer involvement where interpersonal interactions (Townsend & Franks, 1995), mutual sharing of pleasurable meaningful experiences and mentally stimulating activities (Cartwright et al., 1994) and cognitive support by carers (Cavanaugh et al., 1989) are conceptualised as interrelated factors that contribute to carer wellbeing.

3.11 Limitations

The interpretation of these effects is not straightforward, due to the diverse range of studies with small sample sizes, which may have been unable to achieve statistical power. Results may be therefore misinterpreted or fail to produce reliable outcomes (Hackshaw, 2008). For example, of the seven studies included in the meta-analysis, two studies had small samples which ranged from 13 to 16 dyads (Bottino et al., 2005; Onor et al., 2007). Studies with small sample sizes combined with a lack of acceptable standards of sequence generation, allocation concealment, blinding and dropout rates limit conclusions of the analyses undertaken. In addition, a combination of different types of interventions, various levels of carer involvement, duration, intensity and follow-up of the intervention make results difficult to interpret.

Publication bias was not assessed, as there were too few studies within each meta-analysis group. Therefore, there would not be sufficient power to detect true asymmetry (Higgins and Green, 2008). Because CBIs have been predominantly developed to improve cognition and QoL for people with dementia, there is a lack of RCTs comparing two similar interventions where one includes carer involvement and the other does not. Therefore, it is difficult to identify and be specific about the impact of carer involvement in CBIs on carer wellbeing.

3.12 Conclusion

The findings suggest that carer involvement in CBIs may improve carers' QoL and reduce carers' depressive symptoms. These results support the theories of carer involvement where interpersonal interaction, mutual sharing of meaningful experiences and cognitive support by carers may act as mediators of carer wellbeing. Nevertheless, there remains a lack of quality of research in this area. Particularly, in some outcomes, there was a lack of consistency of results, so the findings should be interpreted with caution.

This review also highlights that the current evidence base for carer involvement in CBIs is limited with most of the studies reporting results based on small sample sizes. There are insufficient studies to examine differences between carer involvement in CS, CR and CT. Therefore, larger samples and further high-quality RCTs of carer involvement in CBIs are warranted. There are also no RCTs examining the effects of carer involvement in CBIs in which people with dementia in both the intervention and control groups receive the treatment, but carer involvement is offered in only one of the two groups. Future research should examine the effects of carer involvement where people with dementia in the control group also receive CBIs. Since CBIs are designed to deliver benefit for people with dementia, the

collateral benefits for carers have potential implications for the importance of CBIs in service delivery and may contribute to cost effectiveness of dementia care.

4 Chapter 4 Evaluating the effects of iCST using a mixed methods approach incorporating; a pragmatic RCT and a qualitative study

4.1 An overview of mixed methods

This Chapter describes the methods of my PhD research which was nested into the pragmatic iCST RCT. My PhD research aims to evaluate the effects of carer-delivered iCST for people with dementia on carer wellbeing. In this chapter, I report the use of the Medical Research Council (MRC) framework (Craig et al., 2008) to demonstrate how my PhD work has been built on previous research of CST and highlight the strengths and limitations of the iCST trial methodology.

The MRC framework is used for the development and evaluation of RCTs of complex interventions to improve health (Craig et al., 2008). It consists of five stages: a pre-clinical-theoretical stage, Phase I modelling, Phase II exploratory trial, Phase III definitive RCT and Phase IV long-term implementation. I followed the MRC guidelines and adapted the appropriate stages to evaluate my research. Firstly, I conducted a literature search to establish theories and make hypotheses prior to the clinical phase. The theories and evidence were derived from the carer involvement in CBIs for people with dementia (Cartwright et al., 1994; Cavanaugh et al., 1989; Townsend & Franks, 1995) (see Chapter 2).

In Phase I, I identified and systematically reviewed the evidence base of CBIs such as group CST (Spector et al., 2003), one to one reality orientation therapy (Onder et al., 2005), cognitive training (Quayhagen & Quayhagen. 2001) and cognitive rehabilitation interventions (Clare et al., 2010) to understand the process of change in the outcomes observed in previous research (e.g., cognition and quality of life for the person with dementia, carer wellbeing and the quality of the caregiving relationship).

In Phase II, I derived hypotheses on the effects of a complex intervention prior to a large RCT. This work included 1) the modified Stress Process Model of Pealin (1990) and the development of a theoretical framework of carer involvement in CBIs. The framework proposes three mediators of positive aspects of dyadic interpersonal interactions which included the binding ties theory (Townsend & Franks, 1995), the enrichment process theory (Cartwright et al., 1994) and the scaffolding theory (Cavanaugh et al., 1989) which influence carer wellbeing (Chapter 2), 2) I conducted a systematic literature review to evaluate the effects of carer involvement in CBIs for people with dementia (Chapter 3) and 3) I designed intervention adherence materials specifically carer diaries and adherence questionnaires to ensure the intervention was delivered as intended. This process allowed me to understand and measure carers' knowledge of iCST and the skills related to adopting the iCST key principles; carers' confidence levels and engagement with the person with dementia in delivering iCST.

During Phase III, my PhD research was nested in the iCST pragmatic RCT which evaluated the effects of carer-delivered iCST for people with dementia on carer wellbeing. There are several strengths of adopting a pragmatic RCT design. The RCT is considered as the 'gold standard' for evaluating the effectiveness of interventions, allowing a researcher to eliminate the potential of confounding and bias when evaluating an intervention, maximising internal validity (Lurie & Morgan, 2013). The use of a pragmatic RCT provides opportunities to test for the effects of an intervention in real world practice settings (Schwartz & Lellouch, 2009). This means the iCST trial was designed to evaluate the intervention in a full range of settings comparable to what happens in normal clinical practice. This method maximised applicability and generalisability in order to examine whether the intervention was effective in everyday life settings. However, there are limitations

such as the possibility of heterogeneity of intervention effects in pragmatic RCTs compared to explanatory RCTs. For example, the iCST intervention was delivered by family carers, which may result in variations in carer' skills in delivering the intervention. Therefore, more time and resources may be needed to train family carers to deliver the intervention (Schwartz & Lellouch, 2009).

4.2 Evaluating the effects of iCST for people with dementia on carer wellbeing; a pragmatic randomised controlled trial

4.2.1 Background

Group cognitive stimulation therapy (CST) is an evidence-based intervention associated with benefits for cognition and QoL for people with mild to moderate dementia (Spector et al., 2003). However, as many people may be unable to attend CST groups due to factors such as mobility problems, reluctance to participate in a group setting or the lack of availability of local group CST. A cognitive stimulation (CS) intervention delivered individually by family carers at home is likely to be useful in making the intervention more accessible to people with dementia and their family carers. Evidence shows that CS interventions delivered individually by a family carer may improve cognition in people with dementia (Onder et al., 2005).

In recent years many psychosocial support interventions have been developed for both the person with dementia and their carers (Van't Leven et al., 2013). Moon and Adams (2013) conducted a review on the effectiveness of dyadic interventions for people with dementia and their carers and found that carer involvement in psychosocial interventions might enhance mutual understanding, communication, and wellbeing for both people with dementia and their carers. However, evidence suggests that the inclusion of family carers in psychosocial interventions can be challenging, as in some studies carers reported higher levels of depressive

symptoms when they participated in the interventions alongside their relative (Milders et al., 2013; Zarit, Zarit, & Reever, 1982). The inconsistent findings raise questions about whether carer-delivered cognitive stimulation interventions have any effects on carer wellbeing and the direction of the effect.

Caregiving has a high interpersonal stress component, hence adapting dyadic interpersonal strategies that build and sustain mutuality are suggested to be important (Kramer, 1993). The stress process model (SPM) provides a useful framework to identify predictors of carer stress and proposes coping strategies and social support as potential mediators of carer wellbeing (Pearlin et al., 1990). However, the SPM does not explicitly include dyadic interpersonal interaction components such as mutuality, sharing pleasurable and meaningful experiences and cognitive support by carers. A theoretical framework of carer involvement in CBIs for People with Dementia (Figure 2.3) is developed by expanding the mediators of carer coping strategies and social support in the SPM to explore the effects of carer involvement in CBIs. This theoretical framework consists of the binding ties theory (Townsend & Franks, 1995), the enrichment process theory (Cartwright et al., 1994) and the scaffolding theory (Cavanaugh et al., 1989).

The binding ties theory highlights the importance of the “closeness” and “conflict” of the relationship that helps carers to use positive dyadic interpersonal interactions to meet the changing needs of the person with dementia (Townsend & Franks, 1995). Cartwright and colleagues (1994) suggest that the enrichment process provides carers with opportunities to share meaningful and pleasurable activities with people with dementia that enhance mutuality in the caregiving relationship. During the trajectory of dementia, cognitive support by carers can play an important role in

improving cognitive performance for people with dementia and enhance their competence to achieve their goals (Cavanaugh et al., 1989).

In this study, a theoretical framework of carer involvement in CBIs for people with dementia is proposed for deriving hypotheses for the effects of carer-delivered iCST for people with dementia on carer wellbeing. During iCST sessions for example carers may have opportunities to interact with the person with dementia, share mentally stimulating activities and provide cognitive support. In addition, little is known about the effects of iCST on carer wellbeing as there are no such interventions in the literature.

4.2.2 Aims and objectives

Aim

- To investigate the effects of carer-delivered iCST for people with dementia on carer wellbeing

Objectives

Primary outcome

- To investigate the effects of carer-delivered iCST on carer health-related quality of life

Secondary outcome

- To investigate the effects of carer-delivered iCST on the quality of the carer/patient relationship

4.2.3 Study design

The iCST trial was a multi-centre, single blind, RCT of two-treatment arms; an intervention group and a treatment as usual (TAU) group. All dyads of people with

dementia and their carers were recruited by completing a baseline assessment. Assessments were blind to treatment at 13 weeks and 26 weeks. After recruitment and baseline assessments, people with dementia and their carers were randomly allocated into either the intervention group (receiving three 30-minute weekly sessions of iCST delivered by the carer for 25 weeks) or the control group (receiving treatment as usual for 25 weeks). Primary and secondary measures were completed at three time points; baseline prior to randomisation; first follow-up (FU1) at Week 13 after baseline and second follow-up (FU2) and primary endpoint at Week 26 after baseline (Figure 4.1).

4.2.4 Sample

4.2.4.1 Participants

People with dementia and their family carers ($n = 356$ dyads) lived in the community at baseline and were recruited from different study sites (London, Manchester, Hull, Bangor, Dorset, Devon, Lincolnshire and Norfolk and Suffolk).

4.2.4.2 Study sites

The trial originally planned to recruit participants from London, Manchester, Hull, and Bangor as the four main study sites. In order to obtain a more heterogeneous sample of participants, strengthen the generalisability of the investigation and increase the sample size to provide sufficient power (Chung & Song, 2010), Dorset, Devon, Lincolnshire and Norfolk and Suffolk study sites were added. For the London study site, Barnet, Enfield and Haringey Mental Health Trust (BEHMH) were taken on as Participant Identification Centres (PICs) to supplement recruitment from the North East London Foundation Trust. Researchers in London, Bangor and Manchester were based in universities, whereas those in Hull, Norfolk & Suffolk, Dorset, Lincolnshire and Devon were based in NHS mental health services (Table 4.1).

The London site acted as a co-ordinating centre and provided all training and continuous support to other study sites. Several staff trainings and “refresher” training and unblind researchers’ focus group events were held throughout the course of the trial to accommodate new researchers. This training aimed to enhance treatment fidelity and ensure researchers were trained on all outcomes.

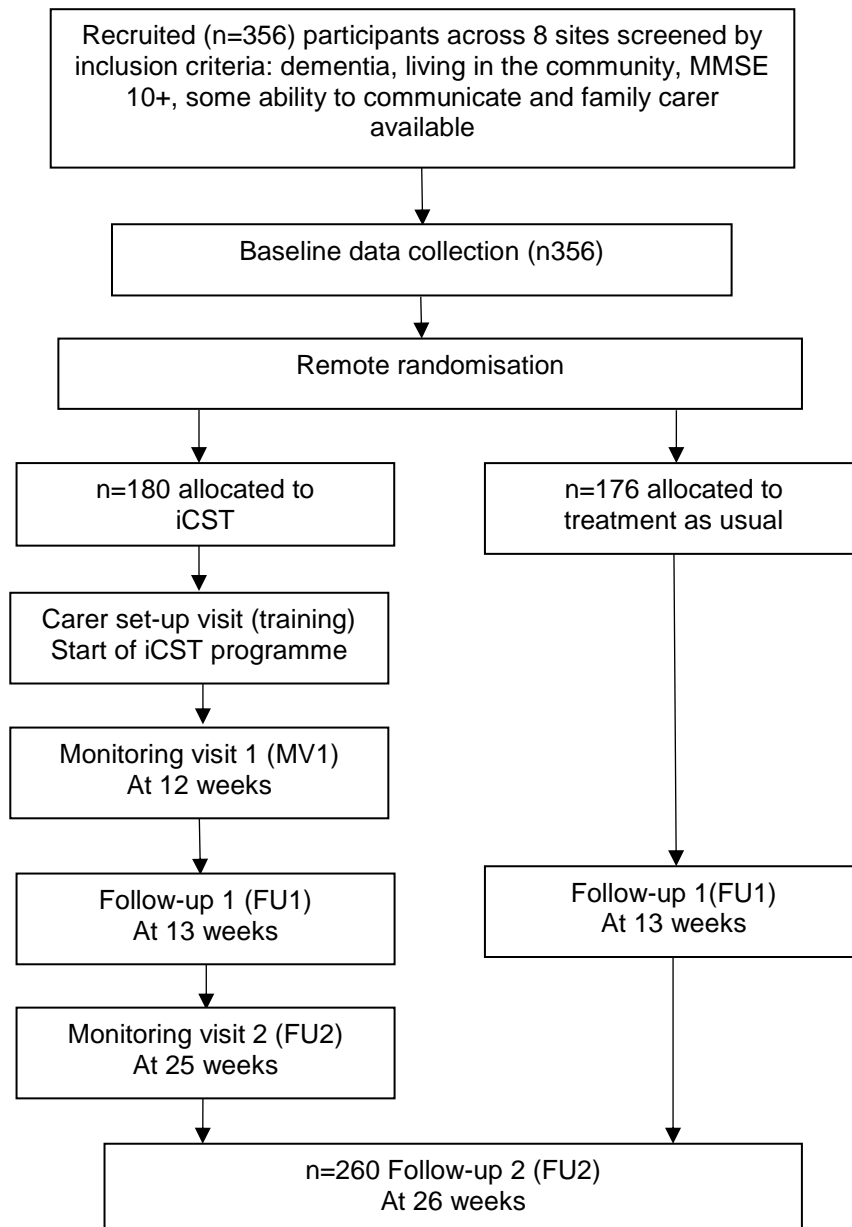


Figure 4.1 iCST trial design showing outcome assessments and intervention visits

4.2.4.3 Sample size

The main analysis was based on intention to treat for the primary outcome ADAS-Cog (cognitive outcome for people with dementia). The trial was initially powered to detect a standardised mean difference (SMD) of 0.35, using a conservative approach, based on previous studies and the Cochrane review. Using a two-group t-test with a 0.05 (two-sided) significance level comparing iCST and TAU with 80% power, gave a sample size of 260. Assuming 15% attrition, the trial was originally proposed to recruit 306 people with dementia. However, the attrition rate was observed to be closer to 25%; thus, the recruitment target was revised upwards by 50 dyads to accommodate this and included recruiting 356 caregiving dyads.

Table 4.1 Study sites in the iCST Trial

iCST study sites	Organisations
London	University College London
	North East London NHS Foundation Trust
	Barnet Enfield and Haringey Mental Health NHS Trust
Bangor	Bangor University
	Betsi Cadwaladr University Health Board
Hull	Humber NHS Foundation Trust
Manchester	The University of Manchester
	Manchester Mental Health and Social Care Trust
	Lancashire Care NHS Foundation Trust
Dorset	Dorset HealthCare University NHS Foundation Trust
Lincolnshire	Lincolnshire Partnership NHS Foundation Trust
Norfolk and Suffolk	Norfolk and Suffolk NHS Foundation Trust
Devon	Devon Partnership NHS Trust
	Northern Devon Healthcare NHS Trust

4.2.5 Inclusion and exclusion criteria

4.2.5.1 Inclusion criteria

All participants were people with dementia who:

- met the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) (American Psychiatric Association, 1994), criteria for dementia of any type (Alzheimer's disease, vascular, Lewy body type and mixed)
- scored 10 or above on the Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975)
- had some ability to communicate and understand communication indicated by a score of 1 or 0 on the relevant items of the Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale (CAPE-BRS) (Pattie & Gilleard, 1979)
- could see / hear well enough to participate in the activities
- had no major physical illness or disability affecting their participation
- lived in the community at baseline
- had regular contact with a relative or other unpaid carer who could act as an informant and could participate in the intervention

An informal carer was defined as an unpaid carer, typically called a family carer who had regular contact with the person with dementia. Regular contact was defined as at least 4 hours per week.

4.2.5.2 Exclusion criteria

People with dementia were excluded if

- they were not living in the community (i.e. living in a care home)
- had no available family carer to deliver the sessions and act as an informant

4.2.6 Recruitment

4.2.6.1 Recruitment procedures

In each iCST site, people with dementia and their family carers were recruited through mental health services for older people, such as Memory Clinics and Community Mental Health Teams, through dementia care professionals, including psychiatrists, and through local voluntary sector organisations, such as the Alzheimer's Society (see www.alzheimers.org.uk). The London, Bangor and Manchester sites were supported by clinical studies officers accessed through the National Institute for Social Care and Health Research-Clinical Research Centre (NISCHR-CRC) in Wales and the Dementias and Neurodegenerative Disease Research Network (DeNDRoN) in England. In Hull and the East Riding of Yorkshire, all patients and carers referred with dementia (and their general practitioners who currently have additional DeNDRoN support to assist with recruitment to dementia trials) were automatically provided with 'opt-in information' on current NHS portfolio studies in dementia care, via a centralised clinical academic unit, The Hull Memory Clinical Resource Centre. The aim of the project was briefly described to potential participants by members of the clinical team and permission for them to be contacted by local researchers was obtained prior to further contact. Research assistants discussed the project and provided full details to participants, answered any questions related to the project, and if participants agreed undertook informed consent.

4.2.6.2 Screening for eligibility

Eligibility to take part was assessed against the specified criteria using a screening checklist (see Appendix 3) which was often administered over the phone by a member of the research team. Once screened, potential participants were sent a letter confirming the date, time and venue of the interview assessment.

4.2.6.3 Screening tools

Since the study only included people with mild and moderate dementia, the Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) score of ≥ 10 and the Clinical Dementia Rating (CDR) (Morris, 1993) which measured severity of dementia.

4.2.6.4 Ethics approval

A protocol was submitted for ethical review to the East London 3 Research Ethics Committee (Ref. no. 10/H0701/71) in January 2010, with provisional approval being granted in July 2010. The following information was identified by the Committee that needed further clarification and amendments:

- Participant Information Sheet (PIS) had to be modified to cover video recordings, information about the control/usual care group and minor editing changes (i.e. language use)

4.2.6.5 Informed Consent

Participants enrolled in the study only after providing informed consent in line with guidelines set by the Mental Capacity Act 2005:

[Great Britain. The National Archives, Mental Capacity Act 2005. URL:

www.legislation.gov.uk/ukpga/2005/9/contents (accessed 14 March 2011)].

Participants were in the mild to moderate stages of dementia, and were therefore expected to be competent to give informed consent for participation, provided that appropriate care was taken in explaining the research and sufficient time was allowed for them to reach a decision. Both people with dementia and their family carers were informed that no disadvantage would accrue if they chose not to participate. All participants were provided with at least 24 hours to review information about the study prior to make a decision. In seeking consent, the RCT followed

current guidance from the British Psychological Society (Dobson et al., 2008) on the evaluation of capacity. In this context, consent was regarded as a continuing process rather than a one-off decision, and willingness to continue participating was continuously checked through discussion with participants during the assessments. At any point where the person with dementia or family carer became uncomfortable with the assessments these were discontinued.

4.2.7 Randomisation

Remote randomisation of participant allocation treatment was undertaken via a web based randomisation service managed by the North Wales Organisation for Randomised Trials in Health (NORTH) Clinical Trials Unit. After baseline assessment and informed consent, randomisation was completed using a dynamic adaptive allocation method (Russell, Hoare, Whitaker, Whitaker, & Russell, 2011), with overall allocation ratio 1:1. Random allocation was stratified by study site and receipt of AChEIs. For each participant randomised the likelihood of their allocation to each treatment group was re-calculated based on the participants already recruited and allocated. This recalculation was done at the overall allocation level, within stratification variables and within stratum level (the relevant combination of stratification levels). By undertaking this re-calculation the algorithm ensured that balance was maintained within acceptable limits of the assigned allocation ratio while maintaining unpredictability.

4.2.7.1 Allocation concealment

The randomisation database was held at NORTH independently of the analysts that were to be involved in the trial. The nature of the dynamic adaptive algorithm used ensured that an accepted level of unpredictability was maintained. Unblind

researchers were the only staff who were informed at each of the iCST study sites of participants' allocation.

4.2.7.2 Blinding

As with all psychosocial interventions participants cannot be blind to the allocation they receive. Within each iCST study site, there were nominated blind and unblind researchers, who were both able to conduct baseline assessments and request randomisation. However once participants were randomised follow-up data were collected by the team of blind researchers only, whilst the training and carer support in delivering iCST was run by unblind researchers. From experience with similar trials, participants might occasionally and inadvertently inform researchers of the intervention they are receiving. In order to reduce this bias, participants were given reminders before follow-up assessment visits not to reveal their involvement in the intervention. All blind researchers were asked to record their impression of the group to which each participant was allocated, and their confidence in that prediction.

4.2.8 The iCST intervention

The iCST intervention was based on a modified CST manual (Spector et al., 2003), the updated CST review (Woods et al., 2012), the study by Onder and colleagues (2005), and consultations with people with dementia, their carers, healthcare professionals and academics (Yates, Orrell, Spector & Orgeta 2015a). The iCST intervention consists of one-to-one structured cognitive stimulation sessions for people with dementia which were delivered either by a family carer or an unpaid carer for 30 minutes, 3 times a week over 25 weeks at home. The intervention consists of 75 cognitive stimulation activity sessions focusing on varied themes such as current affairs, being creative, word games and quizzes (Table 4.2).

Table 4.2 Themes of iCST sessions

■ My life	■ Useful tips
■ Current affairs	■ Thinking cards
■ Food	■ Visual clips discussion
■ Being creative	■ Art discussion
■ Number games	■ Faces/scenes
■ Quiz games	■ Word games
■ Sounds	■ Slogans
■ Physical games	■ Associated words
■ Categorising objects	■ Orientation
■ Household treasures	■ Childhood

4.2.9 Structure of the iCST sessions

The iCST intervention was designed to stimulate cognition for people with dementia. Each iCST session followed a consistent structure, where the first few minutes involved engaging in discussions of orientation information prompted by family carers (i.e. day, date, weather, time, location), followed by discussion of current events (i.e. a news story, a community event, or family occasion), and the main iCST activity (15-20 minutes). In order to accommodate personal interests, dyads were encouraged to adapt the materials provided, and take a flexible approach in relation to choosing sessions, such as omitting any activities not suited to the person with dementia's interests, or revisiting activities that were particularly enjoyable. Carers were trained at the first home visit in delivering the intervention. The person with dementia and their carers were asked to complete up to three 30-minute sessions weekly for a period of 25 weeks.

4.2.10 iCST package

Carers were provided with an 'iCST package' which included the iCST manual and the associated Activity workbook, Carer Diaries and additional toolkit items such as boules, playing cards, dominoes, magnifying card, sound activity compact discs

(CDs), coloured pencils, and world and UK map. All the materials used in the main RCT were assessed for suitability during the development phase of the intervention which included consultations with users and field testing (Yates, Leung, Orgeta, Spector, & Orrell, 2015; Yates, Orgeta, Leung, Spector & Orrell 2016).

4.2.11 The iCST key principles

A set of key principles in delivering the intervention were established based on the guiding principles of CST (Spector et al., 2003) and maintenance CST (Orrell et al., 2014). Carers were instructed to adapt a set of nine key principles during the iCST intervention which included 1) A person-centre approach, which places emphasis on the person with dementia as an individual, 2) Offering choices allowing people to be involved in the activities and be creative, 3) Focusing on opinions rather than facts giving the person with dementia confidence to express their opinions, 4) Using reminiscence helping the person to recall experiences from the past and link with the here and now, 5) Having a tangible focus which helped the person to compensate on their memory loss by the use of visual aids, touching or feeling, 6) Maximising potential refers to giving time, encouragement and cognitive support to the person with dementia, 7) Enjoyment and fun indicated that activities should provide a learning atmosphere which is fun and enjoyable, 8) Stimulating language helped to provide an atmosphere where the person was given the opportunity to contribute and feel valued and respected and 9) Strengthening the caregiving relationship (Table 4.3).

Table 4.3 The iCST key principles

1	Person centred approach
2	Offering choice
3	Focusing on opinions rather than facts
4	Using reminiscence
5	Always have a tangible focus – something to look at, touch or feel
6	Maximising potential
7	Enjoyment and fun
8	Stimulating language
9	Strengthening the caregiving relationship

4.2.12 Treatment adherence, carer training and support

4.2.12.1 Adherence and treatment integrity

Treatment integrity (TI) refers to the extent to which the intervention is delivered as intended. TI has important implications for the validity of conclusions drawn about the obtained effect (Pereplechikova, Treat, & Kazdin, 2007). Lichstein et al. (1994) developed the TI model to ensure clinical psychosocial interventions are delivered as the intended intervention. Three treatment components are described which include 'delivery', 'receipt' and 'enactment'. They are essential in delivering the intervention as intended. Treatment 'delivery' refers to the interventionist's ability to deliver the intervention as specified without adapting it, or incorporating elements of other treatments. 'Receipt' refers to the extent to which the participant received the intervention, and 'enactment' is how far the participant's behaviour has changed. It is essential to provide detailed descriptions of intervention components in accordance to recent guidelines and apply standardised procedures, which is considered as a factor that can increase intervention adherence (Pereplechikova, Treat, & Kazdin, 2007).

Two types of treatment implementation strategies are recommended which are induction methods and assessment methods to maximise TI. The induction method enhances the probability that proper treatment integrity occurs, for example, detailing the intervention in the iCST protocol and the iCST manual for carers reduced the variability in treatment implementation and enhanced TI. The assessment method measuring occurrence of the intended treatment integrity strategies is also important. For example, the Carer Diaries were used to record number of sessions and activities that dyads had completed. This process provided carers with opportunities to evaluate the person's mood and interest on the sessions they completed, as well as carers' impression about the sessions. As a result, this process enhanced carers' treatment adherence.

4.2.12.2 Measures of adherence

The Carer Diaries, adherence questionnaires for carers and adherence questionnaires by unblind researchers were designed to measure adherence to the iCST intervention throughout the trial.

4.2.12.3 Carer Diaries

A carer's diary was designed and developed to help carers monitor sessions completed with the person with dementia. The Carer's Diary was comprised of two parts (Carer's Diary 1 and Carer's Diary 2) and was completed by the carer delivering the sessions. Reporting number of sessions completed by the carer in the iCST Carer's Diary provided adherence data for iCST. 'Carer's Diary 1' (containing sessions 1-32) was given to the dyad at the set-up visit, and was collected by the unblind researcher at the first monitoring visit (Week 12). At this monitoring visit the dyad was given an additional copy of 'Carer's Diary 1' if their first copy was not complete, and a copy of 'Carer's Diary 2' (containing sessions 33-75). The purpose

of splitting the diaries and collecting Diary 1 at the first monitoring visit was to safeguard against loss of data should the dyad withdraw from the study or be uncontactable after the monitoring visit. The remaining diaries were then collected at the second monitoring visit. The Carer Diary required carers to record which sessions had been completed, dates of completion, and assessments of communication, enjoyment and interest experienced by the person with dementia. Ratings of mood were also completed for each theme of iCST (see Appendix 3).

4.2.12.4 Carer adherence questionnaires

The purpose of self-rated carers' adherence questionnaires was to assess intervention adherence. Carers' self-rated adherence questionnaires were completed at three time points; set-up visit, monitoring visit 1 (MV1) and monitoring visit 2 (MV2).

Additional variable measured included: 1) 'Carers' knowledge of iCST' was measured on a 5-point Likert scale (1=poor to 5=excellent), 2) 'Carers' confidence in delivering the iCST sessions' was measured on a 4-point Likert scale (1=very little to 4=very confident), 3) 'Carers' and people with dementia being able to engage in iCST' was measured on a 4-point Likert scale (1=none of the time to 5= all of the time), 4) 'Carers being able to "focus on opinions rather than facts" during iCST sessions' was measured on a 5-point Likert scale (1=none of the time to 5=all the time), 5) 'Carers being able to develop ideas in a sensitive manner during the iCST sessions' was measured on a 5-point Likert scale (1=none of the time to 5=all the time), 6) Carers incorporating their relative's personal interests in iCST was measured on a 5-point Likert scale (1=none of the time to 5=all of the time) and 7) 'I have been able to adapt the sessions to accommodate my relative's abilities' was measured on a 5-point Likert scale (1=none of the time to 5=all the time). An

additional question about support received from the unblind researcher was measured on a 5-point Likert scale (1=poor to 5=excellent)

4.2.12.5 Carer training and support

All family carers randomised to the intervention group received notification of the randomisation result via a standard letter (see Appendix 3). Carers delivering iCST were provided with continuous support in delivering the therapy. There were three types of support: a) iCST set-up visit, b) telephone support and c) monitoring visits (Figure 4.2).

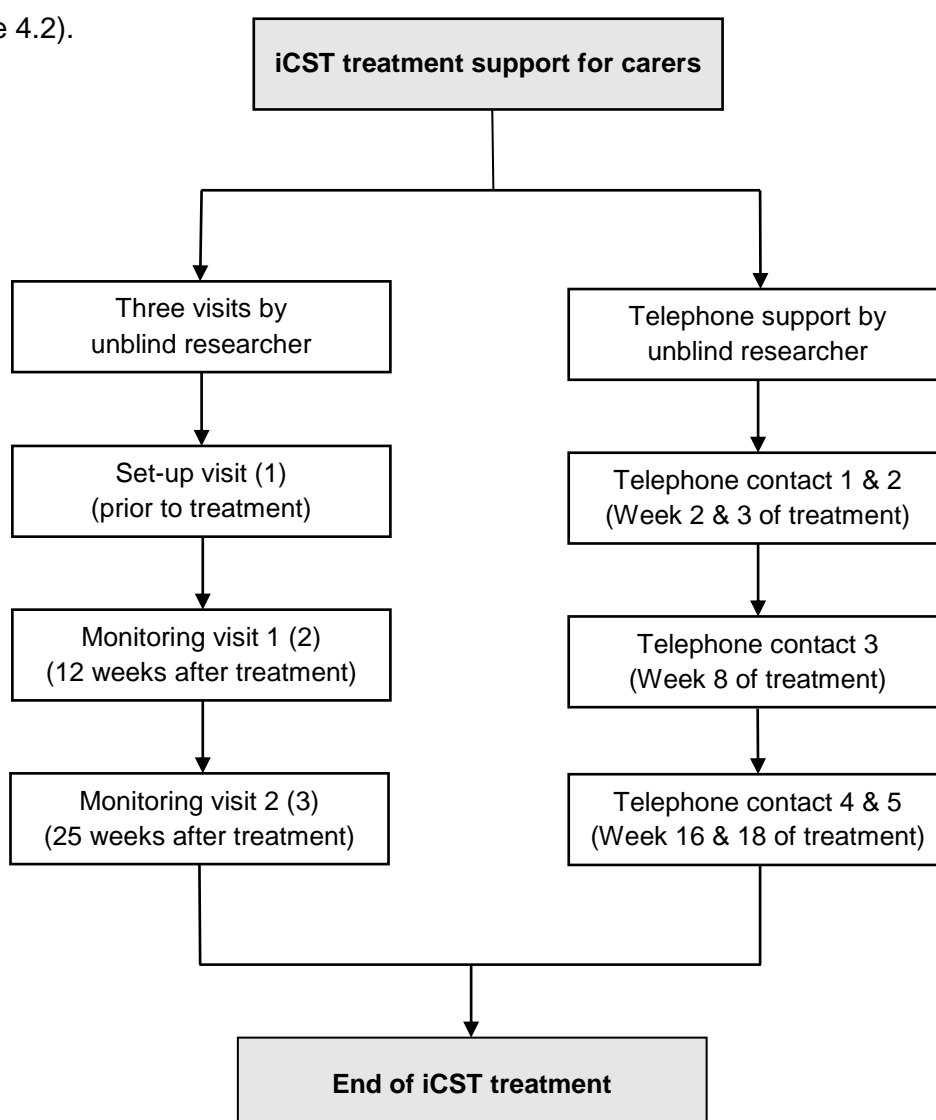


Figure 4.2 iCST flow chart of carer support

4.2.12.6 Set-up visits

Carers received their first set-up visit at their home by the unblind researcher. The set-up visit lasted approximately 1-1 ½ hours. Both the carer and the person with dementia needed to be present for the training.

The set-up visit training was standardised and designed to be interactive incorporating role-play exercises (see Appendix 3), and the opportunity to see clips of the maintenance CST training DVD 'Making a Difference 2' (Spector et al., 2006). The unblind researcher spent the first few minutes showing the carer the iCST package which included the iCST manual, the iCST activity Workbook, the iCST 'Carer's Diary 1' and the iCST Toolkit. Following this, the unblind researcher provided background information of iCST to the carer which covered the development of Cognitive Stimulation Therapy (CST). The carer was trained to tackle the beginning of each iCST session which included discussion of orientation information and current affairs by using the 'Beginning each session' section of the manual as a guide. The unblind researcher discussed with the dyad suitable warm up activities during the first session.

An important part of the set-up training was describing the iCST key principles. The unblind researcher used the 'Putting the key principles into practice' leaflet as a guide for discussion. The unblind researcher showed the dyad one clip of the "Making a Difference 2" DVD. This clip illustrated a group CST 'Art Discussion' session that was delivered by a facilitator using the key principles. Watching the 'Art Discussion' session helped carers to identify any key principles that were used in the clip, or any ways the session could have been improved. After the discussion of the "Making a Difference 2" clip, the unblind researcher went through the two role play exercises with the carer where the unblind researcher took the role of the 'Carer' and the carer

took the role of the 'Person with Dementia'. Exercise 1 demonstrated bad practice in iCST and exercise 2 demonstrated good practice of iCST (see Appendix 3).

At the end of the session, the unblind researcher provided the carer with constructive feedback such as comments on things that went particularly well in the session before pinpointing sensitively areas for improvement. Carers were not told at any point that they had made a 'mistake', or done something 'wrong'.

4.2.12.7 Carer support

An unblind researcher provided dyads with telephone support throughout the sessions. Each carer received regular telephone support (initially weekly), and thereafter as indicated by the carer at the set-up visit. The purpose of the telephone support was to monitor the extent to which participants were adhering to the intervention and whether they required assistance with the sessions. Support was also given, in order to ensure that carers were able to deliver the intervention and to address any issues interfering with delivery. On average five telephone support calls were made to carers (see Appendix 3). The number of calls and time between calls varied depending on the preferences of individual carers. Each carer was informed of the telephone support procedure at the set-up visit, and carers' preferences were reported in order to guide the unblind researcher.

Unblind researchers completed a telephone contact questionnaire, at these five time points throughout the 25 weeks. This was defined as protocol contact. These questionnaires allowed the researcher to report whether the support call was made and if not, the reason why. It also recorded the number of iCST sessions completed, the length of time spent on the sessions, and who was delivering the sessions. If

sessions were not being completed, the areas of difficulty were recorded on this form, and details of any 'out of protocol' contact made were also recorded.

Carers received two monitoring visits, which were scheduled for Week 12 after the start of the iCST intervention and at week 25, to assess adherence. The purpose of the monitoring visits was to collect the iCST carer diaries and complete a brief questionnaire about carers' views in delivering the iCST sessions.

4.2.13 Out of protocol contacts

Dyads were expected to receive up to ten hours of support including a set-up visit, telephone support calls and two monitoring visits during the intervention. An out of protocol contact form was developed to record the details of additional support (see Appendix 3).

4.2.14 Intervention and control conditions

Participants who were randomly assigned to the intervention group received iCST at their home. The control condition was 'treatment as usual' (TAU) with participants in this group receiving no additional intervention. The services and interventions available to people with dementia and family carers randomised to receive treatment as usual varied between and within the iCST centres and may have changed over time.

It is unlikely that any comparable (or even any other) individual cognitive stimulation intervention for the person with dementia would have been available, as these types of interventions are generally unavailable in the UK. It is possible that some participants in the intervention group might have engaged in some form of mentally stimulating activities in day centres, however this is unlikely to have been as

structured as iCST. Study sites were asked to note instances where the person with dementia might have engaged in cognitive stimulation therapy groups by their local services. Participants that had engaged in such activities for a period of three months prior to recruitment were not considered eligible.

4.2.15 Data collection

Primary and secondary measures were completed at baseline, 13-weeks after baseline (Week 13) and 26-weeks after baseline (Week 26). Researchers were instructed to conduct all Week 13 assessments within the 13-week period, but no later than 2 months of the scheduled first follow-up appointment (starting at date of baseline assessment), and all Week 26 assessments at 26-weeks, but no later than 2 months of the scheduled second follow-up.

Most interviews were conducted in the dyads' home. All questionnaire instruments were arranged in the form of booklets, with additional show cards of responses supporting the person with dementia during the assessment. If at any point the person with dementia felt uncomfortable with the assessment this was discontinued or where appropriate it was rescheduled to take place during a second visit.

4.2.16 Outcome measures

4.2.16.1 Carers' primary outcome measure

- a) Carers' physical and mental health was assessed by employing the 12-item Short-Form Health Survey (SF-12) (Ware, Kosinski, & Keller, 1996). The SF-12 Health Survey is an instrument derived from the longer 36-item Short-Form (SF-36) (Ware & Sherbourne, 1992). It is a standardised instrument which includes a total of 12 questions, with three to five answer categories in each question (Likert-type scale).

- b) The instrument consists of eight dimensions of physical functioning, role functioning physical, bodily pain, general health, vitality, social functioning, role functioning emotional, and mental health. The instrument has a physical functioning component score and a mental functioning component score ranging from 0 to 100 with higher scores representing better self-perceived health-related quality of life (HR-QoL) (Ware Jr et al., 1996). The SF-12 is a reliable and valid measure of health status in independent living older adults (Resnick & Nahm, 2001) and carers of people with dementia (Conde-Sala et al., 2014; George & Steffen, 2014).

4.2.16.2 Carers' secondary outcome measures

- a) Depressive symptoms measured by the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). HADS has good validity and reliability (Mykletun, Stordal, & Dahl, 2001) and has been validated throughout the age range and in several settings to identify clinically significant anxiety and depression (Mahoney, Regan, Katona, & Livingston, 2005). The HADS is a self-completed measure, generating scores for generalised anxiety and depression, used widely to identify caseness for clinically significant depression and anxiety. Higher scores on the two HADS subscales indicate the presence of more anxiety and depressive symptoms. The HADS has been employed in several studies to assess carers' anxiety and depressive symptoms (Clare, 2010).
- b) Health-related quality of life using the EQ-5D (Brook 1996). NICE currently recommends the EQ-5D, as a simple, generic, single index measuring HR-QoL. The EQ-5D has five dimensions including mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three

levels: no problems, some problems, and extreme problems. A single index is used to provide values for health status by using a Visual Analogue Scale (VAS) (EuroQoL, 2005). This scale has been validated in community-dwelling populations of older people (Kaambwa et al., 2015; Pettit et al., 2001).

- c) The quality of the caregiving relationship measured by the Quality of the Carer/Patient Relationship (QCPR) (Spruytte et al., 2002), applicable to both spousal and adult child carers, completed by both the person with dementia and their family carer. This measure comprises 14 items using a 5-point Likert-type scale, which range from “totally disagree” to “totally agree”. The scale measures the warmth of the relationship and the absence of conflict and criticism. Items on the criticism and conflict subscale are reverse coded, so that higher scores reflect better relationship quality. The QCPR has good internal consistency and concurrent validity with other measures of relationship quality and carer distress (Spruytte et al., 2002). The QCPR has been used to assess the relationship quality of carers and people with dementia (Woods, 2012).

4.2.17 Data checking

A full data-management plan was written, encompassing data storage, processing, data filing, data sharing, data freezing and data archiving. Data were collected in questionnaire packs and entered a data-management system (MACRO version 4.1.2.3750, InferMed, London), which was audited for data entry accuracy, before being exported to Statistical Package for the Social Sciences (SPSS) files. SPSS Predictive Analytics Soft-Ware version 20 (IBM Corporation, Armonk, NY, USA) was used for all further data manipulations and analysis. In all SPSS files, cleaning

processes were undertaken, including checks for consistency and out-of-range data. If applicable, questionnaire data were cross-checked with the SPSS data to explore any issues of inconsistency.

4.2.18 Data analysis

4.2.18.1 Primary effectiveness analyses

An intention-to-treat (ITT) analysis was carried out, in that all available data was included. Sample size calculations were based on the numbers estimated to be available at the study primary end-point (FU2) 26 weeks after randomisation into the iCST intervention group, or TAU control.

An analysis of covariance model (ANCOVA) was used to assess the differences between the iCST and TAU groups in the primary outcome measure for family carers in the SF-12 Health Survey (physical and mental health components). The dependent variable in the model were the outcome at Week 26, with covariates being the baseline measurement, age of carers and type of relationship with the person with dementia. The fitted fixed factors were gender and marital status. Centre was fitted as a random factor. Fisher's exact test and Mann-Whitney U test were performed to test differences between complete vs. incomplete Follow-Up 2 for carers on demographic factors.

4.2.18.2 Secondary effectiveness analyses

The ANCOVA model described above was used to assess differences between the two groups on all carer secondary outcomes.

4.2.18.3 Additional analyses

A basic adherence analysis was undertaken. Number of iCST sessions completed was held as a continuous variable and added to the model of the main analysis. This would allow an insight as to whether the number of sessions completed was important to the outcome.

4.2.19 Missing data for effectiveness analyses

Data were not imputed for participants who did not provide any information at a specific time point. However, standard statistical tests were employed to ensure that there were no significant differences in demographics or baseline outcome scores between those who completed at a time point and those who did not. There were two types of missing data which were missing items within measures and missing measures at time points.

4.2.19.1 Missing items within measure – pro-rating

For items missing within measures the rules for completing missing data for the relevant measure were applied. The missing data rules implemented for each measure were considered part of the validated tool and were therefore used as designed in line with the original validation. Pro-rating within participant measures were undertaken at the 20% missing level (i.e. for a 5-item score if there was one item missing, this was completed with the mean of the other items).

4.2.19.2 Missing measures at time points

A regression model within the treatment group was applied to impute total scores in line with the trend seen in the group, as multiple imputations, allowing an assessment of the sensitivity of the data. The multiple imputations with a linear regression were carried out for scale variables at baseline. Imputation was performed only one time

considering the small number of missing values in the baseline dataset. At Follow-up 1 (Week 13) and Follow-up 2 (Week 26), repeated multiple imputations were performed 5 times and the pooled results were reported for the outcome. The multiple imputation models included demographic variables such as gender, age, ethnicity, type of relationship and study site. These models also included the completed scores for the other outcome measures at each time point. At both follow-up time points the model included the allocated treatment group. Scores at baseline were used to predict scores at Week 13. Scores at baseline and Week 13 were used to predict scores at Week 26.

4.2.20 Quality control

Compliance with Good Clinical Practice (GCP) standards is a requirement for all Medical Research Council (MRC) and NHS Research and Development (R&D) funded clinical trials (NHS, 1999) and this trial was conducted in accordance to GCP standards. Accurate records were kept in accordance with the protocol laid out in the investigator's manual for recruitment, randomisation and data collection. Data was collected and managed in a systematic and verifiable manner. The researchers were trained, supervised and supported. Data collection was ongoing with a database designed at the outset, to expedite reporting and enable data quality control. Compliance to GCP, protocol and trial processes was monitored monthly in the first year and quarterly subsequently. The Principal Investigator (PI) of each site ensured that careful records of randomisation were maintained via a trial register and that participants' confidentiality was assured. Quality control was applied to a sample of key data items at all study sites and during data entry.

4.3 The experiences of people with dementia and their carers participating in individual cognitive stimulation therapy; a qualitative study

4.3.1 Background

Many randomised controlled trials (RCTs) have evaluated the effects of cognition-based interventions (CBIs) for people with dementia (Bahar-Fuchs, Clare, & Woods, 2013; Woods, Aguirre, Spector, & Orrell, 2012). However, little is known about the experiences of people with dementia and their carers taking part in these interventions. In line with Medical Research Council guidance (Craig et al., 2008), a qualitative study was undertaken to explore the experiences of people with dementia and their carers who participated in the iCST intervention embedded in the RCT.

The use of qualitative methods embedded in RCTs of complex interventions is increasingly recognised as adding value to research studies (Craig et al., 2008; O'Cathain et al., 2014). It can enhance clinical trials in a variety of ways such as providing opportunities to have a better understanding of the effects of interventions and fully utilising participants' experiences (Lewin et al., 2009). These methods help in understanding the experiences, benefits and limitations of interventions (das Nair and Lincoln, 2013; Lewin et al., 2009). In dementia research, qualitative studies has played a crucial role in improving our understanding of living with dementia and its impact on the person with dementia and their family carers (Gibson, Timlin, Curran, & Wattis, 2004). It helps to capture personal meaningful experiences and life values that may not be reported in quantitative studies. These experiences provide insight into the health and social care needs of people with dementia and their carers (Prorok, Horgan, & Seitz, 2013).

A combination of quantitative and qualitative research can potentially capitalise on the respective strengths of quantitative and qualitative approaches (Östlund, Kidd,

Wengström, & Rowa-Dewar, 2011). However, qualitative studies have a different philosophical foundation that supplement but do not replace quantitative methods (Gibson, Timlin, Curran, & Wattis, 2004). In this qualitative study, the semi-structured interviews captured the meaningful experiences of sharing pleasurable and mentally stimulation activities of people with dementia and their carers. Findings may describe the caregiving relationship in an everyday context which may not have been captured by the quantitative findings. Furthermore, the mixed method research approach not only presents the theoretical propositions but also links the original results in an explicit way and helps in understanding how theory and empirical findings in relation to carer involvement in CBIs are related.

4.3.2 Aim

To explore service user perspectives of people with dementia and their carers of the concepts of mental stimulation and experiences of participation in iCST

4.3.3 Methods

Creswell (2006) describes five common types of qualitative research designs which include the narrative approach, phenomenology, grounded theory, ethnography and case studies. The primary aim of the qualitative study was to explore the experiences of people with dementia and their carers taking part in the iCST intervention. After studying the characteristics of the five qualitative approaches which are presented in Table 4.4, I selected the phenomenological approach, as I considered this approach as the most appropriate to analyse my data. The phenomenological approach provides a rich and complete description of an individual's experiences, perspectives and interpretation of taking part in iCST (Donalek, 2004). Findings focused on people with dementia and their carers' beliefs and feelings rather than these being imposed by myself as an interviewer (Creswell 2006).

Table 4.4 Contrasting characteristics of five qualitative approaches (Cresswell 2006)

Characteristics	Narrative research	Phenomenology	Grounded theory	Ethnography	Case study
Focus	Exploring the life of an individual	Understanding the essence of experience	Developing a theory grounded in data from the field	Describing and interpreting a culture-sharing group	Developing an in-depth description and analysis of a case or multiple cases
Type of problem best suited for design	Needing to tell stories of individual experiences	Needing to describe the essence of a live phenomenon	Grounding a theory in the views of participants	Describing and interpreting the shared patterns of culture of a group	Providing an in-depth understanding of a case or cases
Discipline background	Drawing from the humanities including anthropology, literature, history, psychology and sociology	Drawing from philosophy, psychology and education	Drawing from sociology	Drawing from anthropology and sociology	Drawing from psychology, law, political science and medicine
Unit of analysis	Studying one or more individuals	Studying several individuals that have shared the experience	Studying a process, action or interaction involving many individuals	Studying a group that shares the same culture	Studying an event, a programme, an activity more than one individual

4.3.3.1 Design and study population

This was a qualitative study using semi-structured in-depth interviews. A sub-sample of 23 dyads of people with dementia and their carers was selected from the 180 dyads randomised to the intervention group in the iCST trial (Orgeta et al., 2015), regardless of how many sessions they completed. During the baseline assessment, people with dementia and their carers were informed about the iCST qualitative study and were invited to consent to the possibility of participating in the qualitative interview if they were assigned to an intervention group. Unblind researchers made contact with the participants to discuss the qualitative component of the trial after they completed the intervention (at Week 25). The contact was usually at monitoring visit 2 (MV2), via telephone and occasionally via email. The unblind researcher asked participants if they would be willing to take part in an individual interview about their experiences of taking part in the iCST intervention. If participants agreed to be interviewed, a confirmation letter and participant information sheet was sent to them (see appendix 4).

4.3.3.2 Data collection

In this qualitative study, I was not involved in providing the intervention to the participants. I contacted all individual interviews. Semi-structured in-depth interviews took place at the participant's home, with the full interview fully audio-recorded and transcribed verbatim. The interview questions were established by focusing mainly on nondirective questions, with overall duration ranging from 30 to 45 minutes. People with dementia and their carers were asked separately to describe their experiences of taking part in iCST using open-ended questions initially, followed by questions focusing on specific domains. Interviews started with an informal conversation while the dyad welcomed the interviewer in to their home, in order to build up optimal rapport and increase the reliability of the interview

(Nygard, 2006). In the second part, the interviewer went through the participant information sheets with the person with dementia and their family carer and explained the topic areas of the questions.

Interview topics were derived from the literature of CST (Woods et al., 2012) and interpersonal interactions (Townsend & Franks, 1995), sharing pleasurable and meaningful activities (Cartwright et al., 1994) and cognitive support theories (Cavanaugh et al., 1989). The iCST manual and activity workbook were used as visual aids to help the person with dementia and their carer to recall their experience of doing the activities. Key topic areas explored during interviews were the concept of mental stimulation and experiences of taking part in iCST (see Table 4.5).

Table 4.5 Key topic questions

1. Introduction to the topic of mental stimulation
<ul style="list-style-type: none"> • What is mental stimulation? • Why mental stimulation is important? • What types of activities are mentally stimulating?
2. Experiences of taking part in iCST
<ul style="list-style-type: none"> • How would you describe your experiences of taking part in iCST? • What did you find helpful in taking part in iCST? What about your relative? • Have you experienced any changes in everyday life as a result of taking part in iCST? If yes, what has changed for you and your relative? • Have you experienced any changes in your relationship with your relative? If yes, what has changed for you?
3. Barriers to offering iCST
<ul style="list-style-type: none"> • What is likely to hinder you in offering iCST to your relative? Any specific factors? • What is likely to help you succeed in offering iCST to your relative in the future? Any specific factors?

*(Both the person with dementia and their carer were asked to respond to key topics 1 and 2.
Only the carer was asked to respond to key topic 3)*

4.3.3.3 Data Analysis

There are several approaches that have been put forward to analyse qualitative data such as content analysis, discourse analysis or grounded theory analysis. In this qualitative study, the framework analysis (Ritchie & Spencer, 1993) was used to analyse the data. Framework analysis is a flexible tool to analyse qualitative data which allows a researcher to generate themes (Gale, Heath, Cameron, Rashid, & Redwood, 2013). Framework analysis is used in the context of applied research which aims to meet specific information needs and outcomes within a short timescale. It is a suitable and reliable method of qualitative analysis providing a systematic model for managing and mapping qualitative data. It provides clear guidelines for producing a highly structured output of summarising the data that aims to elicit an individuals' experience through several distinct topics but interconnected stages of analysis (Gale, Heath, Cameron, Rashid, & Redwood, 2013).

Framework Analysis includes five key stages: 1) familiarisation and identifying a thematic framework 2) indexing 3) charting 4) mapping, and 5) interpretation which were used in the analysis of my qualitative data. At the familiarisation and identifying a thematic framework stage, I listened to the audio recordings several times to become familiar with the whole interviews. After familiarization, I read the interview transcripts carefully line by line and then imported these into Nvivo and started coding (indexing). Coding aims to classify all of the data so that it can be compared systematically with other parts of the data set (Gale, Heath, Cameron, Rashid, & Redwood, 2013). In the indexing stage, I coded all data points that might be relevant from as many different perspectives as possible. For example, I coded the data by referring to experiences of people with dementia and carers (e.g., concept of

mentally stimulation activities, potential benefits of taking part in iCST and carer experiences in relation to intervention adherence). Some of the codes were predefined based on the proposed theoretical framework of carer involvement in CBIs. I also used an inductive coding approach to ensure important aspects of the data were not missed (e.g., the design and structure of the iCST programme which related to participants' experiences) or run a text search query to find all occurrences of a word, phrase, or concept across my data (see appendix 4).

At the charting stage, data was organised into a more manageable format to facilitate data analysis in the next stage that involved summarising the data by categorising those from each transcript. I worked through the initial codes (see appendix 4) and decided which codes were the most important and created categories by bringing several codes together. I created new codes by combining two or more codes and dropped some of the initial codes. At the theoretical level, I labelled my data by using categories and decided which were the most relevant and how they were connected to each other. I then labelled the categories and the connections between them. A chart of themes and sub-themes was then developed and further modified until the dominant themes emerged (see appendix 4).

The aim of mapping and interpretation is to move beyond data management towards understanding. I 'pulled data together' by identifying key characteristics of the data then mapped and interpreted the data by using spreadsheets to generate a matrix by categorising results that were specific to people with dementia or to carers. Two researchers LY and FH who were also familiar with the analytical framework compared and contrasted styles of summarising in the early stages of the analysis process to ensure consistency.

5 Chapter 5 results of the iCST pragmatic RCT and the qualitative study

5.1 Results of the iCST pragmatic RCT

5.1.1 Participant flow and response rate

5.1.1.1 Recruitment of participants

A total of 1340 people with dementia and their carers (dyads) were considered for recruitment to the study. Of these, 356 dyads were recruited, randomised and comprised the final sample for the study which gave a conversion rate of 27%. The most common reason for loss between referral and randomisation was not wishing to take part in the study which accounted for up to 24% (n=320) of the total referrals. A total of 22% (n=295) of people with dementia did not meet the inclusion criteria and 16% (n=215) did not respond (Table 5.1).

5.1.1.2 Source of referrals

Referrals came from several sources. The main sources of referrals were from memory clinics 45% (n=602), consultant psychiatrists 23% (n=315) and Community Mental Health Teams (CMHTs) 9% (n=119), (Table 5.2).

Recruitment commenced in April 2012 and was completed in July 2013. The 356 dyads gave informed consent to the study and were randomised after completion of the baseline assessment. The sample was randomised on a roughly 1:1 basis, with 180 dyads in the iCST group, and 176 in the treatment as usual group. A total of eight study sites contributed to the recruitment of the study. The four original sites included London, Bangor, Hull and Manchester and recruited 73% (n=260) of the total sample. The four additional sites included Dorset, Devon, Lincolnshire and Norfolk & Suffolk which contributed the remaining 27% (n=96). Table 5.1 provides rates of randomisation for each of the iCST study sites.

Table 5.1 Response rate and losses between referrals and randomisation

Reason	Total (%)
Does not wish to take part	320 (24)
iCST exclusion criteria apply	295 (22)
Dyad has not responded	215 (16)
Could not make contact/reason not known	53 (4)
Not available due to holiday/family/work commitments	33 (2)
Health problems for dyad	21 (2)
Subtotals	937 (70)
Other	
Prefers group activities/does activities at home /considers intervention not suitable	18 (1)
Already participating in similar study	16 (1)
Distressed during interview	4 (< 1)
Family has not discussed diagnosis	3 (< 1)
Moved out of the area	3 (< 1)
Person with dementia has died	3 (< 1)
Subtotals other reasons	47 (3)
Total lost between referral/screening and randomisation	984 (73)
Total number randomised	356 (27)
Total referred or screened	1340

5.1.1.3 Participant flow

The flow of participants throughout the trial is shown in Figure 5.1. The majority of withdrawals from the trial occurred after the baseline assessment and accounted for up to 15% (n=52). A small number of dyads 6% (n=16) were lost to Follow-up 1 (FU1). Treatment allocation in relation to participant flow can be seen in Figure 5.2 Rates of withdrawal and drop-out at Follow-up1 and Follow-up 2 was similar in both the intervention and control groups.

Table 5.2 Source of referrals

Source	Total (%)
Memory Clinic	602 (45)
Consultant Psychiatrist referrals	315 (23)
CMHTs	119 (9)
Clinical Studies Officer DeNDRoN	67 (5)
Consultant Psychologist referrals	57 (4)
Alzheimer's Society	52 (4)
Primary care Dementia Practitioner	41 (3)
Voluntary organisations & other sources	87 (7)
Total	1340

Table 5.3 Referrals and randomisations by study site

Centre	Total referrals	Total randomisations (%)
London	255	127 (50)
Bangor	296	35 (12)
Hull	111	45 (40)
Manchester	482	53 (11)
Dorset	29	20 (69)
Lincolnshire	36	20 (55)
Norfolk & Suffolk	83	28 (34)
Devon	48	28 (58)
Total	1340	356

5.1.1.4 Follow-up (FU) retention rates at FU 1 and FU 2

Retention rates at FU 1 (Week 13)

Between randomisation and Week 13 there were a total of 68 losses (Figure 5.1), of which 52 dyads withdrew totally from the trial after randomisation with the main reasons being dissatisfied with the intervention (n=11), people with dementia not

wishing to participate (n=6) and dyads being disappointed with the randomisation result (n=6). Sixteen of the dyads were not available to complete the Week 13 assessment but indicated availability to complete the Week 26 assessment (Figure 6.2). There were no differential rates of retention between study sites at Week 13 ($\chi^2 = 11.9$; $df = 11$; $p = 0.37$) (Table 5.4).

Table 5.4 Follow-up retention rates for each study site

Centre	Baseline	Completed Week 13 (retention rate) (%)	Completed Week 26 (retention rate) (%)
London	127	101 (79)	96 (76)
Bangor	35	30 (86)	31 (89)
Hull	45	34 (75)	32 (71)
Manchester	53	39 (74)	37 (70)
Dorset	20	18 (90)	18 (90)
Lincolnshire	20	16 (80)	14 (70)
Norfolk & Suffolk	28	26 (93)	23 (82)
Devon	28	24 (86)	22 (79)
Total	356	288 (81)	273 (77)

Retention rates at Follow-up 2 (Week 26)

At Week 26 (Figure 5.1) a further 31 dyads were lost to follow-up, providing a total of 83 losses overall. The retention rate for the trial was 77%, which was the predicted rate used in the updated sample size calculations. There were no differential retention rates between study sites at Week 26 ($\chi^2 = 12.5$; $df = 11$; $p = 0.33$).

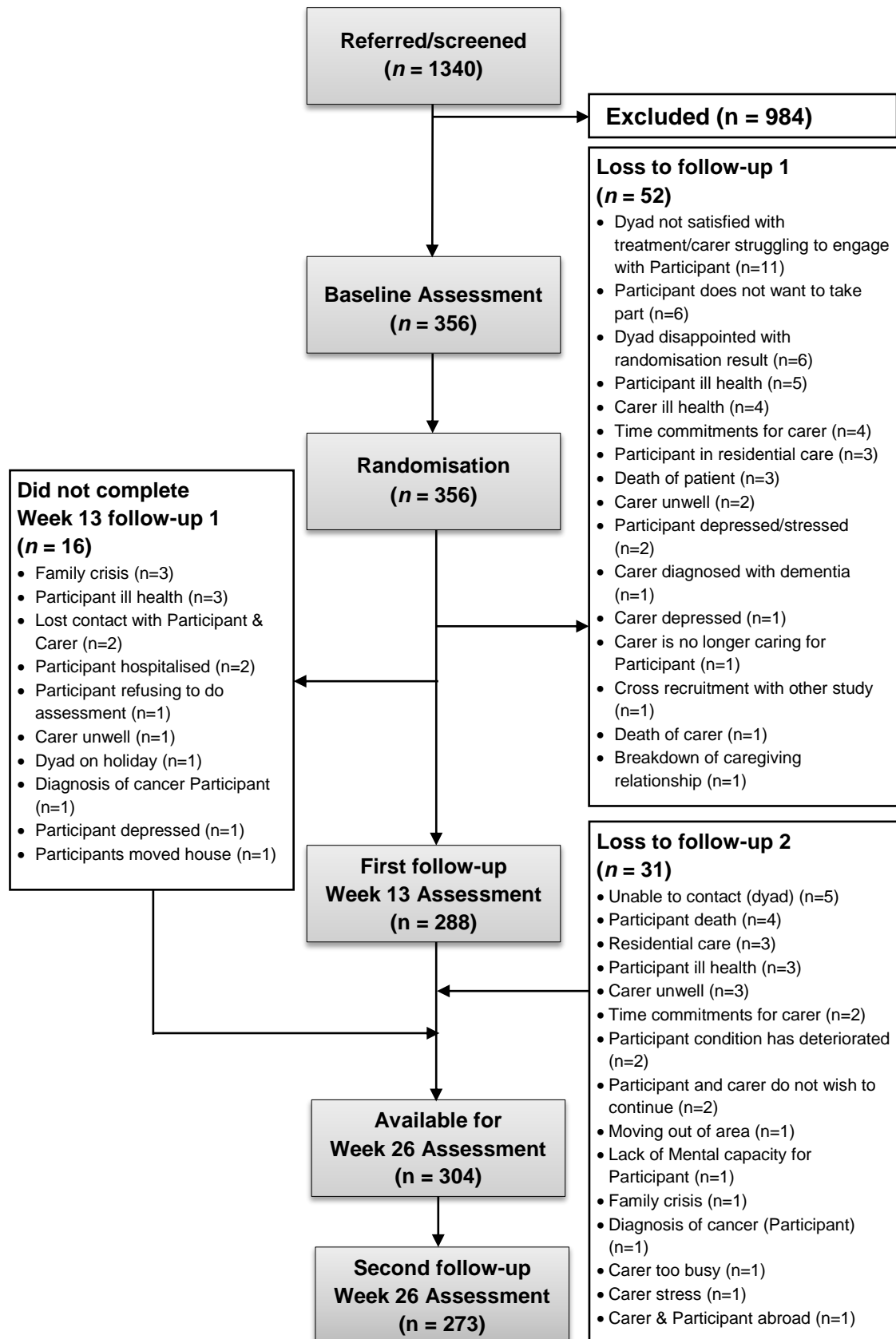


Figure 5.1 Participant flow through the trial

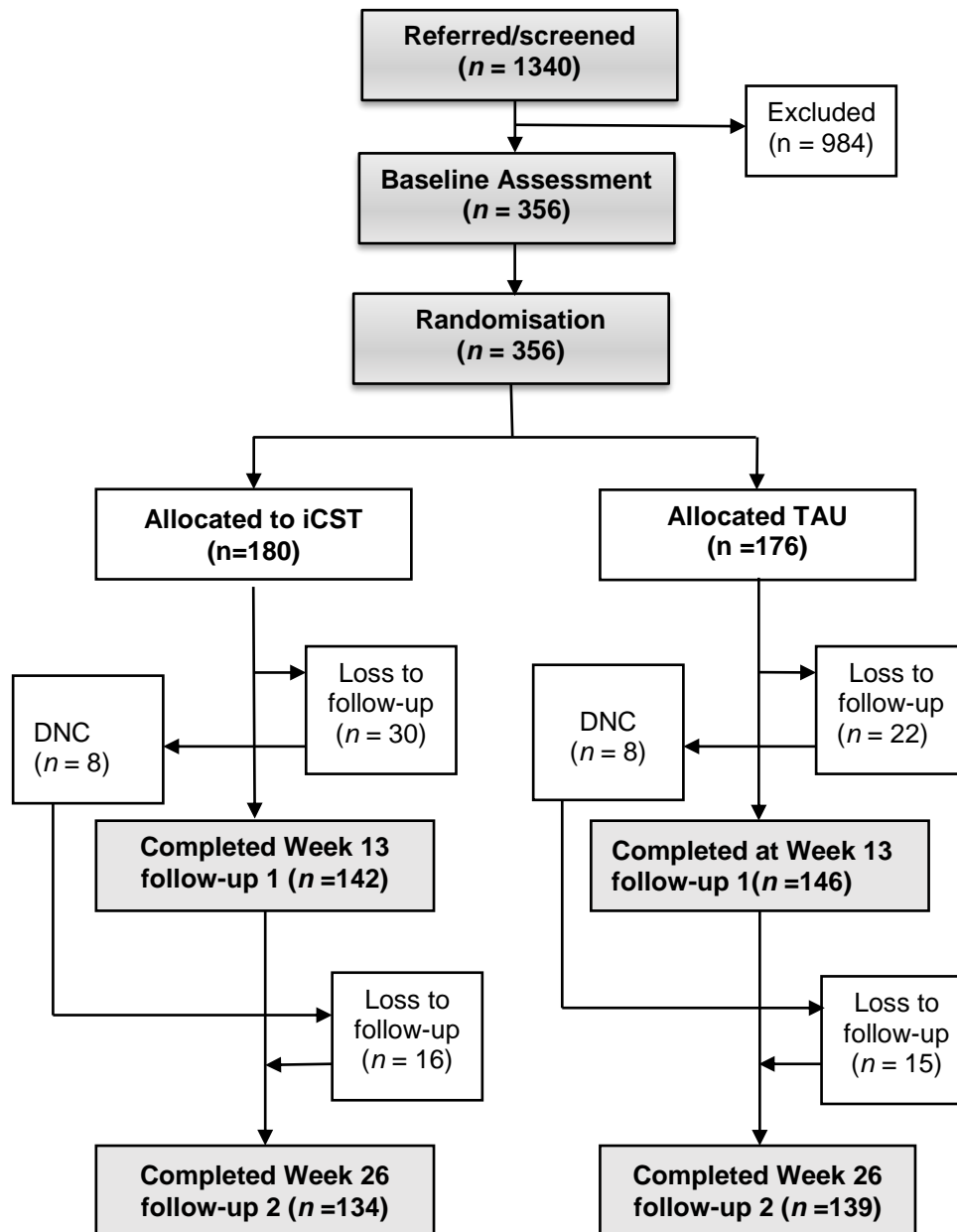


Figure 5.2 Participant flow through the trial indicating treatment allocation.

'Withdrawn' indicates participants' withdrawal from the trial and all associated research activities. 'Did not complete' (DNC) indicates participants who missed FU1 assessment but returned for FU2

Fisher's exact tests and Mann-Whitney U tests were used to analyse whether there were significant differences in baseline characteristics including: gender, ethnicity, marital status, relationship with the person with dementia, living status (e.g., 'with the

person', 'other', 'alone'), and highest level of education. No significant differences were found between the groups.

5.1.1.5 Ratings of perception of allocation of dyads by blind researchers

Blind researchers conducting the follow-up assessments were asked to record whether they thought dyads had been assigned to the iCST or TAU groups on a Likert-type scale ('definitely in iCST group', 'more likely to be in iCST group', 'equally likely to be in iCST or TAU', 'more likely to be in TAU group', 'definitely in TAU group'). A total of 264 perceptions were rated by blind researchers who completed FU1 at Week 13. Table 5.5 shows the results of these perception ratings in terms of the proportion correct. Sixty percent were neutral (equally likely to be in iCST or TAU) suggesting in the majority of cases no evidence of allocation was disclosed to researchers. Twenty-three percent of ratings were correct judgements of allocation, of which 7% of these ratings were a definite judgment and 17% making an incorrect judgment, of which only 5% were definite.

Table 5.5 Researchers' perception of allocation at Week 13

Actual Treatment allocation			
Researcher rating	iCST (%)	TAU (%)	Total (%)
Correct 'Definite' judgment	13 (12)	6 (4)	19 (7)
Correct 'More likely' judgment	14 (13)	28 (18)	42 (16)
Equally likely to be in iCST or TAU	68 (65)	92 (58)	160 (60)
Incorrect 'More likely' judgment	11 (10)	20 (13)	31 (12)
Incorrect 'Definite' judgment	0	12 (7)	12 (5)
Total	106	158	264

Slightly fewer perception ratings (n=255) were collected at FU2 (Week 26) (Table 5.6). However, they remained consistent with the patterns observed at FU1 (Week 13), where 57% of researchers rated treatment allocation equally to iCST and

treatment as usual, with a total of 23% making a correct judgment, of which 10% were definite judgments and 20% made an incorrect judgement.

Table 5.6 Researchers' perception of allocation at Week 26

Actual Treatment allocation			
Researcher rating	iCST (%)	TAU (%)	Total (%)
Correct 'Definite' judgment	22 (19)	4 (3)	26 (10)
Correct 'More likely' judgment	17 (15)	17 (12)	34 (13)
Equally likely to be in iCST or TAU	65 (57)	80 (57)	145 (57)
Incorrect 'More likely' judgment	10 (9)	31 (22)	41 (16)
Incorrect 'Definite' judgment	0	9 (6)	9 (4)
Total	114	141	255

5.1.2 Baseline characteristics analysis

Demographic information

Demographics information of people with dementia and their family carers are presented in Table 5.7, Table 5.8 and Table 5.9 respectively. Table 5.7 provides the means and SDs for age for people with dementia and carers. Overall, the mean age of people with dementia was 78.2 years, of which 46% (n=165) were females. Seventy-one percent (n=252) of people with dementia were either married, cohabiting or in civil partnerships. People with dementia and their carers were predominantly White, which accounted for up to 93% (n=331) (Table 5.8) and 92% (n=329) of the sample respectively (Table 5.9).

The mean age of carers was 65.7 years. There were 223 spousal and 130 non-spousal caregiving dyads. A total of 226 (60%) were wife/husband (Spouse) or partner, 31.70% of carers (n=113) were their son/daughter, son/daughter-in-law or

their sibling (brother/sister). The remaining 2.5% (n=9) were described as 'other relationship' or 'other relative' 2.2% (n=8). At baseline 270 people with dementia were taking AChEIs, roughly equal numbers in iCST (n=136) and TAU (n=134) demonstrating stratification in the randomisation model was effectively distributed.

Table 5.7 Summary statistics of age (in years) for people with dementia and carers

	Total		iCST		TAU	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Person with dementia	356	78.2 (7.49)	180	78.40 (7.30)	176	78.00 (7.70)
Carer	353*	65.73 (12.92)	179	66.01 (12.76)	176	65.49 (13.11)
Spousal carer	223	72.80 (7.89)	112	73.11 (7.57)	111	72.5 (8.22)
Non-spousal carer	130	53.66 (10.80)	67	54.13 (10.67)	63	53.16 (11.00)

*There were missing data for age for three carers

Table 5.8 Person with dementia demographics

Characteristic	Total (%) (n=356)	iCST (%) (n=180)	TAU (%) (n=176)
Female person with dementia	165 (46)	83 (50)	82 (50)
Ethnicity: White	331 (93)	164 (50)	167 (50)
Marital Status: married/cohabiting/civil partnership	252 (71)	125 (50)	127 (50)
Lives with spouse/partner	225 (63)	113 (50)	112 (50)
Highest level of education school leaver (14-16 years)	213 (60)	113 (53)	100 (47)
Taking AChEIs	270 (76)	136 (76)	134 (76)

AChEIs= anticholinesterase inhibitors

Table 5.10 shows gender combinations for the caregiving dyads. The majority of people with dementia 54% (n=191) were males and 46% (n=165) were females, while 73% (n=261) of carers were females and 27% (n=95) were males.

Table 5.9 Carer demographics

Characteristic	Total (%) (n=356)	iCST (%) (n=180)	TAU (%) (n=176)
Female carer with dementia	261 (73)	135 (52)	126 (48)
Ethnicity: White	329 (92)	164 (50)	166 (50)
Marital Status: married/cohabiting/civil partnership	297 (84)	149 (50)	148 (50)
Lives with spouse/partner	236 (66)	119 (50)	117 (50)
Highest level of education school leaver (14-16 years)	156 (45)	79 (50)	80 (50)

Table 5.10 Details of the gender factor in caregiving dyads

Gender of person with dementia		
Gender of carer	Female	Male
Female	82	179
Male	83	12
Total	165	191

Details of dementia diagnosis for the sample are provided in Table 5.11. A total of 64% (n=227) had a diagnosis of Alzheimer's disease alone, followed by vascular 13% (n=40) or Alzheimer's disease in combination with vascular dementia (10%, n=36).

The severity of dementia was measured by the Clinical Dementia Rating Scale (CDR) (Hughes et al., 1982) and general cognition with the Mini-Mental State Examination (Folstein, Folstein, & McHugh, 1975). A total of 70% of the sample had a CDR of 1, 18% a CDR of 0.5, 12% a CDR of 2, whereas one person with dementia received a score of 0. Total mean MMSE scores for the sample was 21.23 (SD =

4.30), with those allocated to iCST scoring a mean of 21.12 (SD = 4.48), and those allocated to treatment as usual scoring a total of 21.33 (SD = 4.11).

Table 5.11 Details of dementia diagnosis

Diagnosis	Total (%) (n=355)	iCST (%) (n=179)	TAU (%) (n=176)
Alzheimer's	227 (64)	108 (60)	119 (68)
Vascular	40 (11)	18 (10)	22 (13)
Lewy body	11 (3)	5 (3)	6 (3)
Mixed Alzheimer's and vascular	36 (10)	22 (12)	14 (8)
Not known	41 (12)	26 (15)	15 (8)

5.1.3 Analyses of outcomes for carers

Analysis of covariance (ANCOVA) was performed for each of the measures. The 26-week primary end point of the study (FU2) was the dependent variable, and the centre was used as the random factor in the model. Marital status, living status, the gender of the participant, use of anticholinesterase inhibitors and treatment allocation were the fixed factors. Age, baseline outcome score, and the type of dyad's relationship were fitted covariates in the model. The same model was applied to outcomes at the shorter-term 13-week follow-up (FU1).

Table 5.11 shows the mean values for the iCST and TAU groups at baseline (BL), 13-week, and 26-week. Data from the outcome measures for the iCST and TAU groups at FU1 and FU2, including ANCOVA group means, mean differences, number of cases with missing data, 95% confidence intervals (CIs) of mean differences, and *p*-values after adjusting for baseline outcome measures and covariates are shown in Tables 6.12 and 6.13. Complete case data is presented, as there was little difference between imputed value data and complete data.

A regression model analysis was performed in which the entire data set ($n=356$) at each point was imputed. Different methodology can be applied to different types of missing data (e.g., death, illness). However, all missing data was treated with the same imputation method. There was no significant difference between the results of the original data and imputed model data.

5.1.3.1 Primary outcome for carers

Analysis showed no statistically significant difference in the primary outcome of SF-12 for carers between iCST and TAU at either Week 26 for physical component (MD=0.46, 95% CI -1.21, 2.13, $p\leq 0.59$) and mental component (MD=-0.13, 95% CI -1.65, 1.91, $p\leq 0.89$) (Table 5.12) or Week 13, physical component (MD=-0.06, 95% CI -1.45, 1.33 $p=0.93$) and mental component scores (MD=-0.71, 95% CI -2.34, 0.92 $p\leq 0.39$) (Table 5.13).

5.1.3.2 Secondary outcomes for carers

At Week 26 the EQ-5D calculated utility value for carers was significantly better for the iCST group with a mean difference of 0.06 (95% CI 0.01 to 0.10, $p\leq 0.014$). At Week 26 there was an indication for the HADS depression subscale to be lower in the iCST group with decreases in depressive symptoms of -0.51 (95% CI -1.09 to 0.08, $p\leq 0.090$) but this did not reach statistical significance.

There were no significant differences between the groups for all other secondary outcomes including the quality carer/patient relationship (QCPR) at Week 13 (Table 5.13) and Week 26 (Table 5.12). In view of these results, the QCPR measure for carers had the most missing data. Table 5.14 shows the imputation analyses for this measure with the final two columns showing the range of F values for the 5 imputed data sets. The suggestion from the observed data that the QCPR warmth subscale

may have an effect was not substantiated by the imputed data set with a pooled mean difference of -0.65 (F-range 2.35-3.66, p range 0.06 to 0.13).

Table 5.12 Unadjusted means for each of the outcomes for iCST and TAU at each time point

Outcome measure	Baseline				Week 13				Week 26			
	N	iCST	N	TAU	N	iCST	N	TAU	N	iCST	N	TAU
	Mis	N=180 Mean (SD)	Mis	N=176 Mean (SD)	Mis	N=142 Mean (SD)	Mis	N=146 Mean (SD)	Mis	N=134 Mean (SD)	Mis	N=139 Mean (SD)
Carer												
SF-12 Physical component	1	51.46 (10.25)	1	50.20 (10.32)		51.13 (9.73)		49.97 (10.34)		50.06 (10.53)	1	48.63 (10.87)
SF-12 Mental component	1	49.42 (8.10)	1	48.14 (9.42)		47.98 (9.90)	2	47.93 (9.96)		48.88 (9.41)		47.88 (10.13)
HADS total	3	9.63 (6.11)		10.02 (6.67)	1	10.37 (6.98)		10.41 (6.89)	1	10.06 (6.92)		11.16 (7.59)
HADS Anxiety	3	5.84 (3.58)		6.03 (3.88)	1	6.33 (4.35)		6.06 (4.00)	1	6.03 (4.32)		6.36 (4.44)
HADS Depression	3	3.79 (3.30)		3.99 (3.40)	1	4.03 (3.30)		4.36 (3.48)	1	4.03 (3.29)		4.80 (3.81)
EQ-5D health state today	3	78.37 (16.63)		76.24 (19.28)	1	78.13 (16.84)		76.45 (16.93)		78.63 (17.09)		76.58 (16.90)
EQ-5D calculated utility	1	0.83 (0.20)		0.81 (0.21)	1	0.82 (0.20)		0.79 (0.22)	2	0.82 (0.21)		0.75 (0.25)
QCPR total	3	59.21 (6.67)	3	58.21 (6.63)	8	60.12 (6.33)	4	59.73 (6.67)	9	60.14 (6.54)	4	59.76 (6.77)
QCPR Warmth	3	34.94 (3.77)	3	34.59 (3.64)	8	35.20 (3.66)	4	35.69 (3.45)	8	35.25 (3.57)	4	34.95 (3.51)
QCPR Criticism & conflict	3	24.26 (3.63)	2	23.63 (3.81)	8	24.92 (3.57)	4	24.04 (4.41)	9	24.90 (3.66)	4	24.81 (4.01)

iCST= individual Cognitive Stimulation Therapy group, TAU=Treatment as usual group, Mis= number of missing cases after pro-rating within items, SD=Standard deviation

Table 5.13 The pooled means (& 95% CI) of the multiple imputations comparing the iCST and TAU for carer outcomes at Week 26 after adjusting for the baseline outcome measures

	Missing	iCST (N= 134)	TAU (N=139)	MD	95% CI of MD	p value
SF-12 Physical component	1	49.57	49.11	0.46	(-1.21, 2.13)	0.59
SF-12 Mental component	0	48.44	48.31	0.13	(-1.65, 1.91)	0.89
HADS total	1	10.27	10.96	-0.70	(-1.85, 0.46)	0.24
HADS Anxiety	1	6.09	6.30	-0.21	(-0.94, 0.52)	0.57
HADS Depression	1	4.16	4.67	-0.51	(-1.09, 0.08)	0.09
EQ-5D health state today	0	78.20	76.99	1.21	(-2.14, 4.57)	0.48
EQ-5D calculated utility value *	2	0.82	0.76	0.06	(0.01, 0.10)	0.01
QCPR Total	13	59.65	60.21	-0.56	(-1.93, 0.82)	0.43
QCPR Warmth	12	35.05	35.13	-0.08	(-0.84, 0.68)	0.83
QCPR Criticism & conflict	13	24.65	25.05	-0.40	(-1.19, 0.39)	0.32

iCST= individual Cognitive Stimulation Therapy group, TAU=Treatment as usual group, MD=Mean difference, * **Significant difference at 5% level**

Table 5.14 The pooled means (& 95% CI) of the multiple imputations comparing the iCST and TAU for carer outcomes at Week 13
after adjusting for the baseline outcome measures

	Missing	iCST (N= 142)	TAU (N=146)	MD	95% CI of MD	p value
SF-12 Physical component	0	50.51	50.57	-0.06	(-1.45, 1.33)	0.93
SF-12 Mental component	2	47.59	48.30	-0.71	(-2.34, 0.92)	0.39
HADS total	1	10.47	10.31	0.16	(-0.81, 1.15)	0.74
HADS Anxiety	1	6.34	6.05	0.29	(-0.35, 0.91)	0.37
HADS Depression	1	4.13	4.27	-0.14	(-0.67, 0.39)	0.60
EQ-5D health state today	1	77.55	77.00	0.55	(-2.59, 3.69)	0.73
EQ-5D calculated utility value	1	0.81	0.79	0.02	(-0.02, 0.06)	0.19
QCPR Total	12	59.90	59.94	-0.04	(-1.45, 1.37)	0.95
QCPR Warmth	12	35.10	35.78	-0.68	(-1.44, 0.08)	0.09
QCPR Criticism & conflict	12	24.80	24.16	0.64	(-0.23, 1.53)	0.15

iCST= individual Cognitive Stimulation Therapy group, TAU=Treatment as usual group and MD=Mean difference

Table 5.15 Results of the imputation analyses for the QCPR scores with more than 5 missing values

iCST =142 TAU = 146					Median F				Low F		High F	
Carer		<i>N mis</i>	Pooled Mean	Pooled Std. Error	Pooled Mean Difference (iCST – TAU)	Pooled Std. Error	F	p	F	p	F	p
QCPR Total	iCST	8	59.73	0.51	-.087	.708	.017	.897	.005	.944	.097	.756
	TAU	4	59.81	0.50								
QCPR Warmth	iCST	8	35.05	0.28	-.650	.392	2.900	.090	2.353	.126	3.660	.057
	TAU	4	35.70	0.27								
QCPR Criticism & conflict	iCST	8	24.68	0.32	.565	.441	1.681	.196	1.257	.263	2.115	.147
	TAU	4	24.11	0.31								

iCST= individual Cognitive Stimulation Therapy group, TAU=Treatment as usual group, Mis= Missing number of participants

5.1.4 Adherence analysis

5.1.4.1 Carer compliance

There was a wide range in terms of number of sessions completed by people with dementia. On average, dyads completed just less than half (31.68) of the recommended number of sessions (75) over 25 weeks. Figure 5.3 shows the number of sessions completed by the 180 participants randomised to receive iCST available for analysis. Overall, 22% of participants did not complete any sessions, whereas 51% completed more than 30 sessions. Intention to treat analyses is not sensitive to variations in receipt of an intervention. Therefore, using all available data including that of dyads who received less or none of the planned intervention, may have underpowered the study against a potential significant result.

A number of options was explored in terms of the best way to consider analyses for adherence. These included whether or not an average of 1.5 or 2 sessions per week had been completed up to Week 13 and Week 26. The most efficient approach was considered to be the total number of sessions completed at each time point.

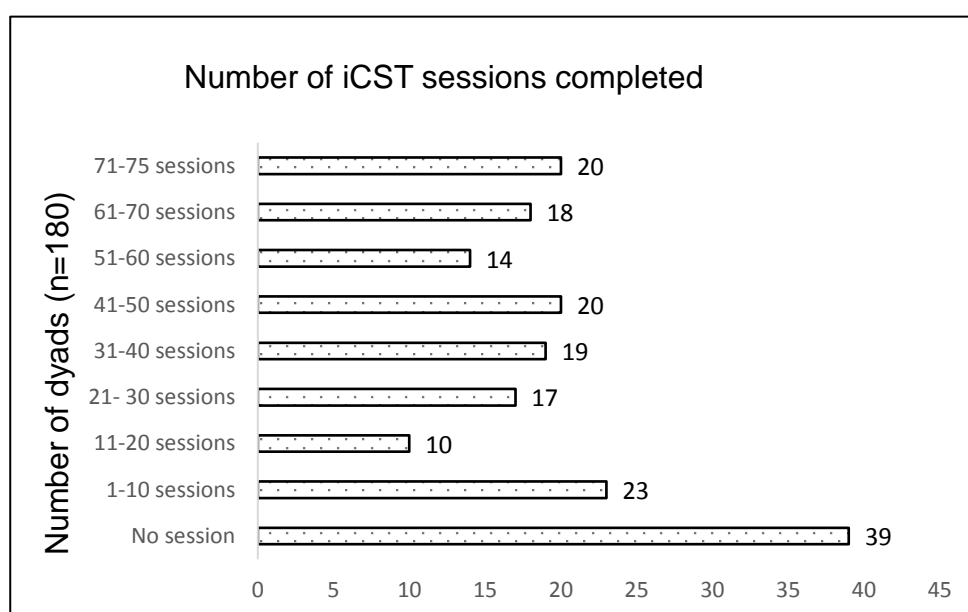


Figure 5.3 Figure Numbers of iCST sessions completed

A linear regression model was used to assess the relationship between the follow-up outcome measures and the number of iCST sessions completed after adjusting for baseline outcome measures. Table 5.15 and Table 5.16 shows the pooled coefficient, standard error (SE), F-value (median, low, high) and p value for the observed and imputed data for carer outcomes at each time point.

There were no significant associations between the primary outcome SF-12 and number of sessions completed at neither time point (Week 13 and Week 26). At Week 26, the HADS depression scale showed a statistical significant reduction in the iCST group ($p \leq 0.02$) suggesting a higher number of iCST sessions were associated with a decrease in depression scores (Table 5.15). The EQ-5D utility scores showed a trend in favour of iCST ($p \leq 0.09$). At Week 13 there were no significant associations between the secondary outcomes and the number of sessions completed, however, there was borderline significance for carer EQ-5D health state scores being associated with higher adherence ($p \leq 0.06$) (Table 5.17).

Table 5.16 The regression coefficient (& SE) of the relationship between each carer outcome measure and the number of sessions of iCST completed at Week 26 after adjusting for the baseline outcome measures

	Observed data				Imputed data							
Week 26					Pooled coefficient	SE	median F		low F		high F	
Carer	coefficient	SE	F	p			F	p	F	p	F	p
SF-12 Physical component	.018	.016	1.196	.275	.017	.016	1.052	.306	1.171	.280	1.253	.264
SF-12 Mental component +	.017	.017	.921	.338	.017	.017						
HADS total *	-.020	.011	3.463	.064	-.022	.011	4.085	.044	3.850	.051	4.815	.029
HADS Anxiety	-.007	.007	1.156	.283	-.009	.007	1.655	.199	1.279	.259	2.091	.149
HADS Depression *	-.013	.006	5.684	.018	-.014	.006	6.275	.013	5.549	.019	6.667	.010
EQ-5D health state today +	.020	.032	.406	.525	.020	.032						
EQ-5D calculated utility value	.007	.004	2.888	.090	.007	.0004	2.992	.085	2.691	.102	3.006	.084
QCPR	-.006	.013	.179	.673	-.004	.013	.065	.798	.010	.919	.184	.669
QCPR Warmth subscale	-.001	.007	.002	.988	.001	.007	.019	.890	.001	.982	.044	.833
QCPR Criticism & conflict	-.004	.008	.273	.602	-.003	.008	.229	.633	.060	.806	.326	.568

iCST= individual Cognitive Stimulation Therapy group, TAU=Treatment as usual group, SE= Standard Error. * **Significant difference**, + When there is no missing data the imputed data columns are left blank

Table 5.17 The regression coefficient (& SE) of the relationship between each carer outcome measure and the number of iCST sessions completed at Week 13 after adjusting for the baseline outcome measure

Week 13	Observed data				Imputed data							
	coefficient	SE	F	p	Pooled coefficient	SE	median F		low F		high F	
							F	p	F	p	F	p
Carer												
SF-12 Physical component +	.015	.030	.270	.604								
SF-12 Mental component +	.007	.034	.040	.843								
HADS Total	-.024	.021	1.271	.260	-.023	.021	1.235	.267	1.219	.271	1.310	.253
HADS Anxiety	-.012	.013	.806	.370	-.011	.013	0.752	.387	0.716	.398	.847	.358
HADS Depression	-.014	.011	1.519	.219	-.014	.011	1.496	.222	1.450	.230	1.667	.198
EQ-5D health state today	.126	.066	3.689	.056	.127	.066	3.773	.053	3.582	.059	3.796	.052
EQ-5D calculated utility value	.001	.001	2.573	.110	.001	.001	2.566	.110	2.558	.111	2.607	.108
QCPR total	-.004	.030	.022	.883	-.003	.030	0.033	.855	0.002	.968	.088	.766
QCPR Warmth	-.008	.017	.223	.637	-.006	.017	0.074	.786	0.020	.888	.466	.495
QCPR Criticism and conflict	.005	.019	.061	.806	.004	.019	0.070	.792	0.001	.980	.206	.650

iCST= individual Cognitive Stimulation Therapy group, TAU=Treatment as usual group, SE= Standard Error.

5.1.4.2 Carers' adherence to the intervention

A total 173 carers at the set-up visit, 141 at MV1 and 124 at MV2 completed the self-rating questionnaires to assess adherence to the intervention. Some carers did not complete the self-rating questionnaires, because they dropped out before the set-up visit or monitoring visits. The carer self-rating questionnaires were developed for this trial to assess carers' knowledge of iCST, confidence, engagement and application of specific techniques and skills in delivering iCST (see Appendix 3).

IBM SPSS version 22 software was used for the paired t-test analysis of carer adherence to the intervention assessments at varied time points that included the set-up visit, MV1 and MV2.

The findings show that carers' knowledge of iCST improved at MV2 compared with the set-up visit with mean difference MD=0.734, SE=0.051, 95% CI 0.632 - 0.836, $t=14.29$, $df=123$ $p\leq 0.001$ (Figure 5.4).

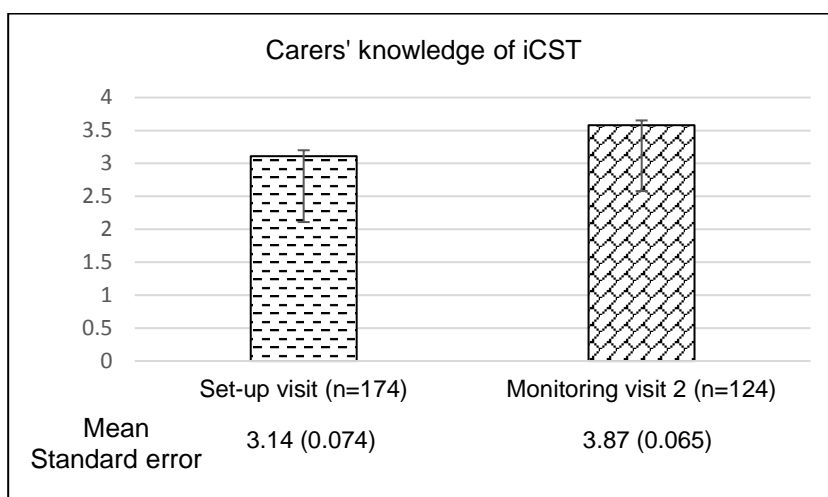


Figure 5.4 Carers' knowledge of iCST

Carers reported that their confidence in delivering iCST improved at MV2 compared with MV1 with MD=0.25, SE=0.039, 95% CI 0.173 - 0.327, $t=6.403$, $df=123$, $p\leq 0.001$ (Figure 5.5).

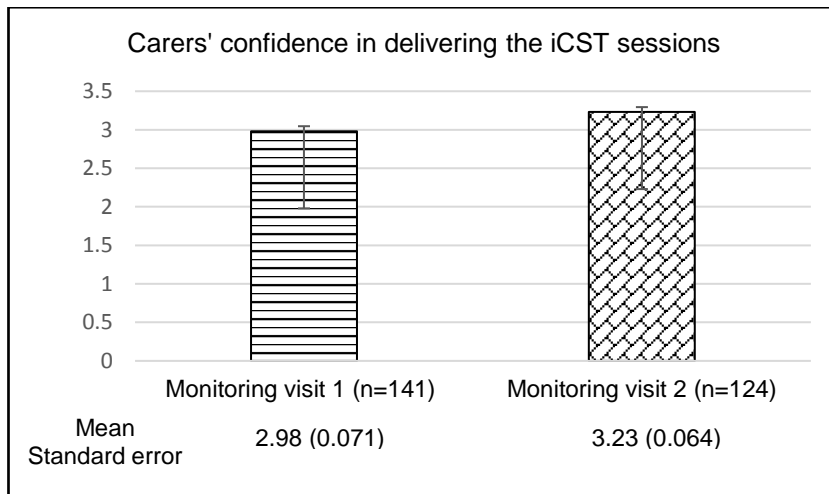


Figure 5.5 Carers' confidence in delivering the iCST sessions

Carers reported significant improvements in using the key principles of focusing on opinions rather than facts at MV2 compared with MV1 with MD=0.089, SE=0.026, 95% CI 0.038 - 0.139, $t=3.460$, $df=123$ and $p\leq 0.001$ (Figure 5.6).

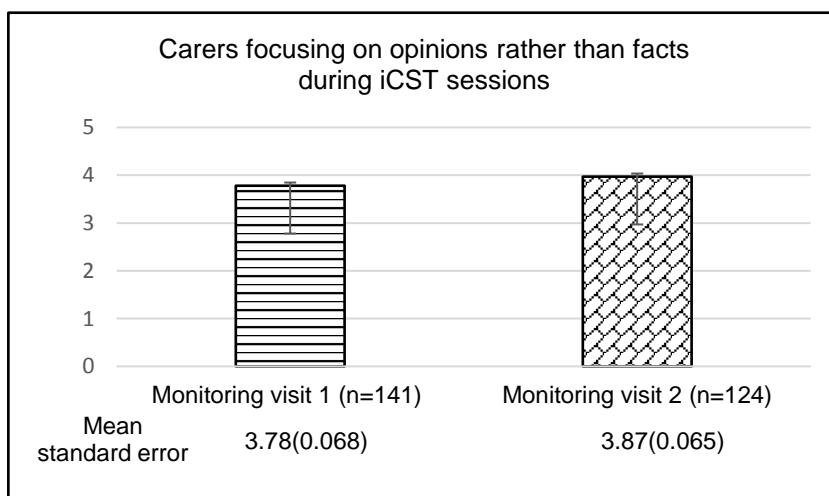


Figure 5.6 Carers focusing on opinions rather than facts during the iCST sessions

Carers showed improvements in developing ideas in a sensitive manner when they delivered the iCST sessions to their relative at MV2 in comparison to MV1 with MD=0.145, SE=0.032, 95% CI 0.082 - 0.208, $t=4.570$, $df=123$ and $p\leq 0.001$ (Figure 5.7)

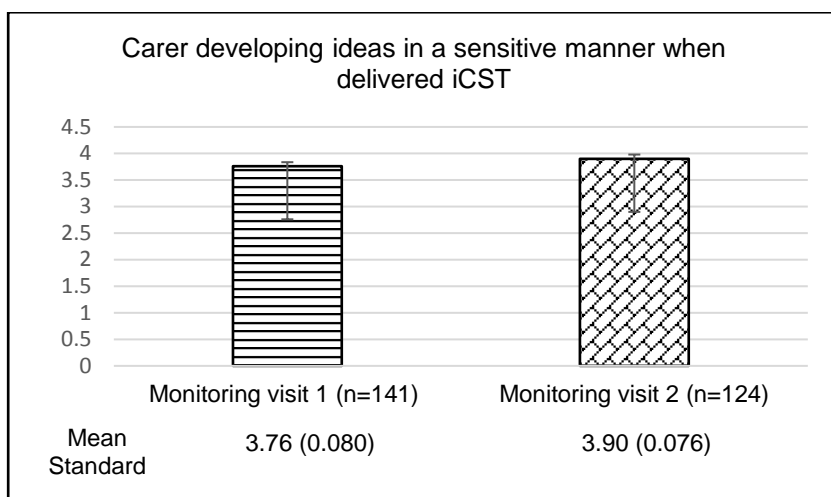


Figure 5.7 Carers developed ideas in a sensitive manner when they delivered the iCST sessions

Carers incorporating their relative's personal interests in the iCST activities showed an improvement between MV1 and MV2 with MD=0.153, SE=0.038, 95% CI 0.078 - 0.229, $t=4.026$, $df=123$ $p\leq 0.001$. (Figure 5.8)

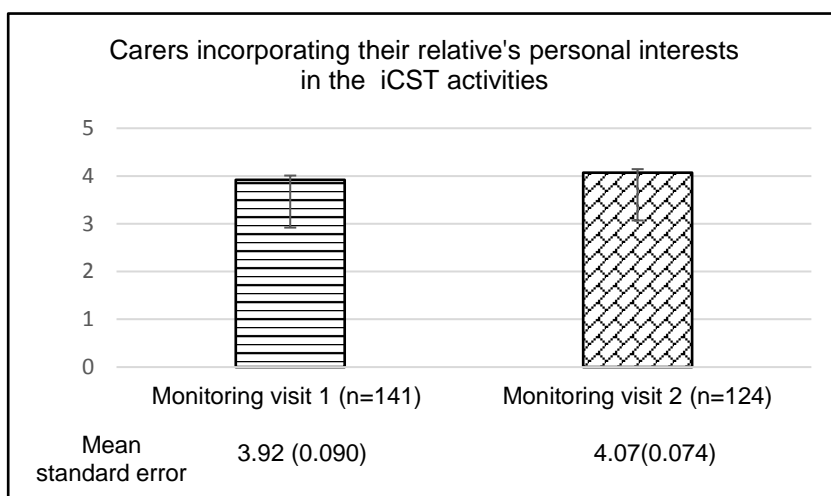


Figure 5.8 Carers incorporating their relative's personal interests in the iCST activities

An increase in carers reporting of adapting the sessions to accommodate the person's ability was observed at MV2 in comparison to MV1 with MD=0.089, SE=0.036, 95% CI 0.017 - 0.160, $t=2.448$ and $p\leq 0.016$ (Figure 5.9).

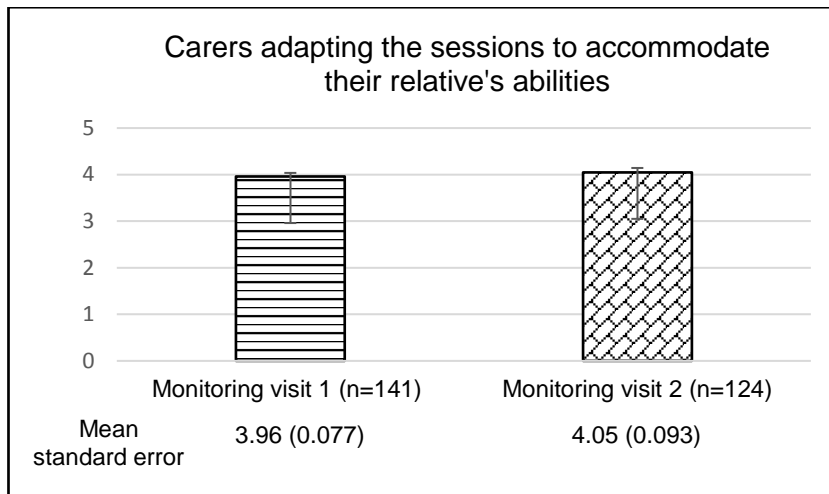


Figure 5.9 Carer adapting the sessions to accommodate their relative's abilities

At the set-up visit, 83% (n=144) of carers anticipated that they and their relative would be able to engage in the sessions “most the time” or “all the time”. However, there was no significant difference in levels of engagement at MV2 in comparison to MV1 with MD=-0.016, SE=0.026, 95% CI -0.067 - 0.034, $t=-0.631$, $df=123$, $p\leq 0.529$ (Figure 5.10), as reported by carers.

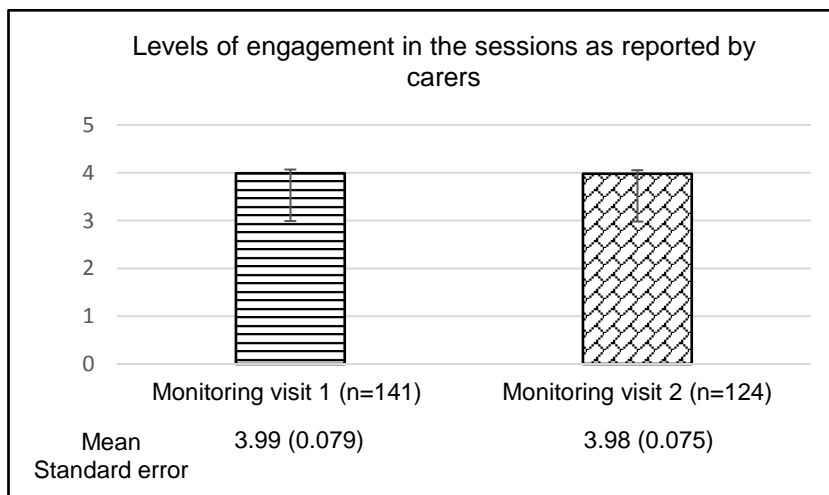


Figure 5.10 Levels of engagement in the sessions as reported by carers

5.1.4.3 Carer support

At the set-up visit, 70.5% (n=122) of carers indicated that they would only need “a little” support and 9.8% (n=17) that they would not need any support from unblind

researchers. At MV1, 80.9% (n=114) of carers rated the support they received from unblind researchers as good or excellent. Overall carers were satisfied with the support provided by unblind researchers which increased significantly at MV2 in comparison with MV1 with MD=0.12, SE=0.032, 95%CI 0.059 - 0.183, $t=-3.834$, $df=123$, $p\leq 0.001$ (Figure 5.11).

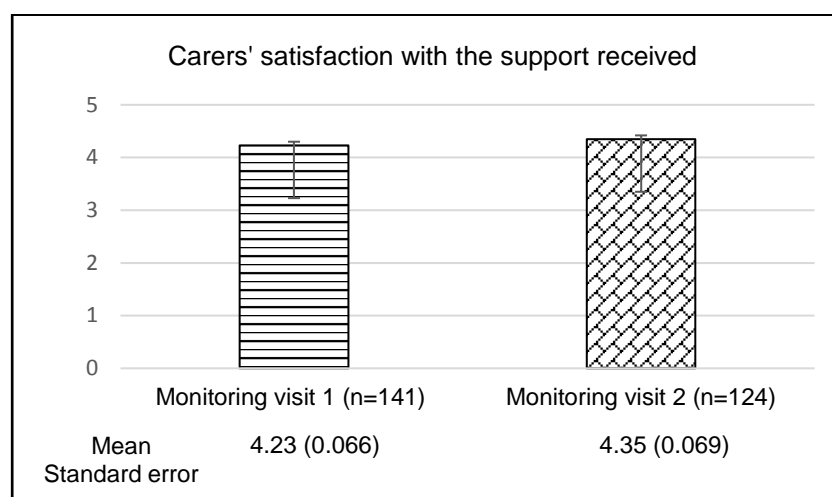


Figure 5.11 Carers' satisfaction with the support received from unblind researchers

5.2 Findings of iCST qualitative study

A total of 35 dyads in the intervention group were approached to take part in the qualitative study. Twelve dyads were excluded because of ill health, family crisis, reluctant to take part or because they completed far fewer sessions than recommended. Data saturation was reached after analysing 23 dyads (Marshall, 1996). Of these 23 dyads, ten dyads were recruited from London, four from Manchester, five from Norfolk & Suffolk and four from Dorset. The mean age of people with dementia was 74.7 years, and 65.9 years for family carers. People with dementia had a mean baseline Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) score of 22.5. There were 17 spousal carers, five adult-child carers, and one sibling carer. The average number of iCST sessions completed was 49.4. The minimum number of sessions completed was 18, and the maximum was 75, with 61% of the sample completing more than 38 sessions (Table 5.18).

Table 5.18 Demographic characteristics of people with dementia and their family carers

	People with dementia n = 22	Carers n = 23
	Mean (SD) Mean [%]	Mean (SD) Mean [%]
Age	74.7 (6.00)	65.9 (13.68)
Age range	From 65 to 84	From 32 to 86
Gender		
Male	16 [73]	4 [17]
Female	6 [27]	19 [83]
Ethnicity		
White British	15 [68]	20 [87]
Other White European	4 [18]	2 [9]
Caribbean	3 [14]	1 [4]
Education		
School leaver (14-17)	12 [55]	10 [43]
School leaver (18 years of age)	4 [18]	2 [9]
Higher education	4 [18]	6 [26]
Further education	2 [9]	5 [22]
Mean MMSE at baseline	22.5 (3.38)	
Mean number of iCST	49 (18.38)	
iCST session range	From 18 to 75	

The analyses identified three main themes and ten sub-themes. The main themes were a) “concepts of mental stimulation”, b) “experiencing changes in everyday life as a result of taking part in iCST” and c) “carers’ adherence to the intervention”. (Table 5.19)

Table 5.19 Main themes and sub-themes merging from the interviews

Main themes	Sub-themes
Concept of mental stimulation	Effects of mentally stimulating activities
	Types of mentally stimulating activities
Experiencing changes in everyday life as a result of taking part in iCST	Opportunities for mental stimulation
	Opportunities to communicate
	Enjoyment and pleasant activities
	Being active in everyday life
	Brought the carer and the person with dementia 'together'
	Carer's awareness of the 'needs' of the person with dementia
Carer adherence to the intervention	Barriers to implementing the intervention
	Factors increasing intervention adherence

5.2.1 The concept of mental stimulation

5.2.1.1 Effects of mentally stimulating activities

Most people with dementia perceived mental stimulation as activities that provided opportunities to keep the *"brain going"*, think, reflect, concentrate and stay alert and talked about the importance of "If you don't use it you lose it".

"It gives an opportunity to think, reflect, review words and understand them, to reflect on what you want to say and what you're hearing somebody else saying and about the whole situation"

(Person with dementia)

"Keep brain working or it will stagnate then deteriorate... by using the brain more, memory should increase"

(Person with dementia)

Results indicated that mentally stimulating activities are important to people with dementia and suggested that mental stimulation provided opportunities to learn new information.

“so I think that (mental stimulation) helps the person with dementia to be in the moment and be in the present, even though they might be talking about things in the past, they are relating to something in the here and now... I do feel that is really important.... It helps to think for new things or think about things in a slightly different way”

(Carer)

5.2.1.2 Types of mentally stimulating activities

People with dementia and their carers mentioned a broad range of activities that they considered as mental stimulation, which were categorised into thirteen different themes (Table 5.20). Engaging in conversation and games/puzzles were amongst the most popular suggested activities. Both people with dementia and their carers suggested practical tasks and outdoor activities that helped them to stay mentally active and enhance their wellbeing.

“I like making things with my hands, just to keep my mind stimulated”

(Person with dementia)

People with dementia and their carers emphasised on the importance of maintaining a sense of connection to family, friends, and the wider community such as having grandchildren around or being involved in voluntary work.

However, taking part in these activities was perceived as challenging for people with dementia since they would probably *“get stuck”* and *“lose interest”* without their carers' encouragement.

“Absolutely, you need somebody like that (carer), I mean, you couldn’t do it on your own, I think you would be helpless or something and I would give up after the first page... you do need that push”

(Person with dementia)

Carers also perceived their involvement to be very important as it provided opportunities for them to interact and build “rapport” with their relative.

“Because if (the person with dementia) had been left alone with the book he would have got stuck and maybe lost a bit of interest and wondered away from it ...prompt each other a little bit well in an indirect way... so I think it is important actually”

(Carer)

Table 5.20 Types of mentally stimulating activities

• Art & Craft	Painting, drawing, making masks or making cards
• Conversation & communication	Talking to others, discussing politics or current affairs
• Cultural interests	Going to the theatre or a concert
• Music	Playing piano, accordion, singing or listening to music
• Outdoor activities	Social outings, walking, walking a dog, driving or cycling
• Physical activities	Exercise, bowling, leisure games
• Practical tasks	Shopping, cooking, gardening
• Problem solving	Managing and organising
• Quizzes/games	Word games, board games, crossword, word search or Dominoes
• Reading	Reading books, poems or newspaper
• Religion	Going to church or praying
• Reminiscing	Sharing meaningful past events
• Social contact	Family, friends and community (i.e. attending meetings or being involved in voluntary work)

5.2.2 Experiencing changes in everyday life as a result of taking part in iCST

5.2.2.1 Opportunities for mental stimulation

Seventy percent of people with dementia (n=16) and sixty-five percent of carers (n=16) reported that iCST provided opportunities for general mental stimulation and non-specific memory improvement. People with dementia described their experience of mental stimulation as feeling alert, and that the intervention helped them in terms of raising general 'awareness of what is happening' and helping them to 'think better'. Some people with dementia experienced changes in their memory.

"It helped to try and get my memory back and look at different things"

(Person with dementia)

Sometimes iCST was perceived as a learning course for cognitive stimulation.

"The course has re-stimulated me to think" and "It does sharpen up what you are doing"

(Person with dementia)

Taking part in the iCST intervention also motivated people with dementia to keep their mind active and look for more information about mental stimulation.

"...It varied the awareness of what is happening I think, otherwise just carry on not thinking about things but then get aware of what it is all about and start thinking a little bit more about it"

(Person with dementia)

"Makes me more inquisitive and enlightens me about things"

(Person with dementia)

It also helped people with dementia to focus on thinking.

*“It does obviously get your mind focused on trying to think of the past
as well, very interesting”*

(Person with dementia)

Taking part in iCST helped people with dementia to realise that their memory was not completely lost.

*“I think it woke me up a little to say you can still use it. That is the
main point as well”*

(Person with dementia)

Some people with dementia spoke about their memory and the need to stay mentally active.

“Well I want to try and fight it as much as I can”

(Person with dementia)

Some carers noticed their relative was more active and alert.

*“I notice the difference in my mum considerably when she is taking
part in lots of activities...her alertness, her ability to then be involved
in more things and just generally she seems to benefit from that”*

(Carer)

Participating in iCST motivated people with dementia to maintain or learn new skills in daily life and gain confidence.

*“One time we made the bread, I turned around and he was washing
up...I noticed that if something has come off, it gives him more*

*confidence, he has a little bit more about him, you know, he is not just
shrivelling away, he comes out of himself"*

(Carer)

A carer showed a photo of the cake which was made by her husband during the iCST cooking session.

*"I'm going to show you that (a photo of the cake), he made that, he's
never made a cake in his life (iCST cooking session)"*

(carer)

However, nearly twenty percent of people with dementia (n=4) did not find iCST stimulating enough and said the activities were too easy.

"I didn't honestly find the material all that stimulating for me"

(Person with dementia)

*"Silly things (the activities) they're asking you, they didn't help me
think better"*

(Person with dementia)

Although some people with dementia and carers said the activities were not challenging enough, they were aware that the intervention was probably designed to meet the needs of a wide range of people.

*"I enjoyed but I didn't gain much from it, because a lot of it wasn't
appropriate for my particular stage of difficulty, you must have so
many people at different stages, with different needs"*

(Person with dementia)

5.2.2.2 Opportunities to communicate

The iCST intervention provided opportunities for people with dementia and their carers to engage in conversations and discussions which they wouldn't normally have with each other.

*"If it hadn't been in there we wouldn't have thought to do
them and now open the book, being in there we did get to
discuss them"*

(Person with dementia)

Carers reported that engaging the person with dementia in conversation can be difficult, taking part in iCS, however helped frame their conversation and discussion with their relative to *"stimulate the mind"*.

*"A pack with activities to help stimulate the mind of the person with
dementia and help the carer find new ways of communicating and
talking to that person"*

(Carer)

5.2.2.3 Enjoyment and pleasant activities

Eighty-two percent of people with dementia (n=19) found iCST enjoyable. They described the activities as pleasurable, entertaining, and interesting. Some participants mentioned that they did not remember the activities, but they were able to reflect on the enjoyment of taking part.

"I don't remember the activities, but I enjoyed what we were doing"

(Person with dementia)

For some people with dementia, the feelings of enjoyment and achievement were more salient than their memory of specific activities or sessions they took part.

“I have felt I have done something when it is time to pack up, and put the things away...I enjoy doing them... feel you’ve accomplished something”

(Person with dementia)

“Yeah even though like things might not stay with me..., but it's brilliant.”

(Person with dementia)

The intervention provided carers with opportunities to interact with the person with dementia and felt their involvement was not a burden, but enjoyable.

“We don’t have a lot to say, this gives us time to talk together. It wasn’t a burden, it was fun.”

(Carer)

“I think we both really enjoyed it and I think some work better than others, but it was a good way of sitting down having some time dedicated to actually talking about our particular subject or something specific, and I think that was helpful and it was fun as well.”

(Carer)

5.2.2.4 Being active in everyday life

People with dementia reported that being involved in iCST encouraged them to take up new activities, feel motivated and being aware of “things around” them.

*"It makes you aware of what is going on... It just keeps you going
otherwise you would slump away and sleep the day away."*

(Person with dementia)

People with dementia and their carers applied iCST in their everyday activities. One couple made a journey to their hometown to remember what had changed since they left.

*"We were going through the street of that town, trying to remember
each shop."*

(Person with dementia)

For some people with dementia taking part in iCST was an 'obligation', which has helped them not only to 'think better', but also to engage in other activities. A few people with dementia found some of the activities helped them to revisit activities/hobbies they enjoyed in the past or look for new activities and interests.

*"It's made me start thinking about doing what I used to do which was
painting..., over there there's about two or three paintings over
there..., that I've done on that table. I think I could do more painting
and that might make me better, you know and I can get up and do
things more easily."*

(Person with dementia)

Carers also experienced changes in their everyday life such as having 'more of a focus' or looking for further information related to mentally stimulating activities for their relative.

*"I noticed a difference in his memory. Helps him remember daily
activities more, e.g. washing, getting a drink."*

(Carer)

“He became a little more active, more willing to participate in discussions, activities that we did together outside of the activities in the book. He tended to snooze a lot before.”

(Carer)

The iCST intervention was perceived as providing a “break” for carers from everyday routine.

“It gives you a break from everyday life because while you're doing this, you're concentrating on doing that, therefore your mind relaxes from other problems... with this it makes him think and I've noticed a difference. When he was doing that, you see, that helped him think of normal ordinary daily living things.”

(Carer)

5.2.2.5 Brought the carer and the person with dementia ‘together’

Most people with dementia reported that iCST brought them “closer together” with their relative. Taking part in iCST enabled people with dementia to see “*another side of their carer*”. A better understanding of their carer helped keep their “relationship going”.

“It brings you together in a very nice way and it is good. ...we ought to continue them because it does get you together.”

(Person with dementia)

Carers emphasised that spending time doing iCST together with their relative gave them the opportunity to share meaningful experiences.

“...Just opening topics of conversation, maybe listening to her, encouraging her to express herself and talk about things.... All that kind of stuff that is quite tedious and I think it is nice to just have the time to sit down and spend half an hour just looking through some photos or looking at a book together.”

(Carer)

Carers found that doing iCST together with their relative helped keep their “relationship going”.

“it's keeping the relationship going and although I can see that there can be changes in the relationship, doing these kind of activities together cements it and makes you stay involved in each other's lives.”

(Carer)

5.2.2.6 Carer's awareness of the 'needs' of the person with dementia

Engaging in iCST provided carers with opportunities to interact with the person with dementia and be more aware of their needs.

“On the whole the experience has been really good... It disciplined us... so I think it raised an awareness of the needs of my husband”

(Carer)

In addition, being involved in iCST helped to raise carers' awareness of situations that their relative was likely to encounter in everyday life.

“I did not really notice any drastic changes...but the main changes were in how I was probably relating to her and thinking about how she would understand things, and how that could be in everyday

*situations... The change is probably more about me that I noticed
about her"*

(Carer)

5.2.3 Carers' adherence to the intervention

5.2.3.1 Barriers to implementing the intervention

Carers identified several factors that hindered taking part in activities such as time, living arrangements and health problems.

*"We might have had a problem with identifying the time to sit down
and organise ourselves."*

(Carer)

Some adult-children carers found it hard to fit in sessions as they were not living with their parents.

*"Harder for me because I don't live with my mum, I see her only
probably three times a week"*

(Carer)

Physical health problems or low mood hindered people with dementia to engage in the sessions.

*"Only the period when he was reluctant and I suppose that was also
tied to him having an emotional response to his condition anyway."*

(Carer)

*"So some of the days that were bad were possibly because it was
physical problems"*

(Carer)

Taking part in iCST gave carers the opportunity to reflect on the progressive nature of dementia.

“It is so easy to be negative and very difficult to be positive because you know when you are working with somebody, he isn't going to get better.”

(Carer)

Some carers felt that the activities did not always match the cognitive needs of the person with dementia.

“At the beginning of where it says talk about the weather, talk about the latest news and the time of year. I think she probably found this quite frustrating, why are you asking me the day or why are you asking me what the weather is like, and the news she rarely now remembers anything that is in the news.”

(Carer)

Carers found that the “benefits” of activities varied and that this depended on the topics, the person’s interests and issues around “level” of cognitive impairment.

“Sometimes it is difficult, depending on the topic, on the subject, the reaction is quite different sometimes.”

(Carer)

A few carers found their approach and communication skills in delivering the sessions could hinder engaging with the person with dementia.

“That is a bit of a disadvantage in a way because I have started off this and for goodness sake take your teachers voice I was thinking off because I was teaching him like a little boy in school.”

(Carer)

“I think it could be easy to make it a bit threatening for the other person if you're implying that there is a right answer or that they should be remembering something and I think it is really important that the carers understand that is not how it works.”

(Carer)

The information provided about dementia at the set-up visit was viewed as a barrier for carers to deliver the iCST intervention.

“For us the diagnosis is quite new. We have not really been given much information in general, so perhaps a little bit of information..., especially to kind of understand what is happening to her, and then doing something like this.”

(Carer)

5.2.3.2 Factors increasing intervention adherence

Carers suggested having more help to deliver the intervention by involving other people was key.

“Involvement with other people, it would be a great aid”

(Carer)

Peer support was also seen as a potential successful extra source of support.

“Another way of looking at it I suppose is if there is anyone else in the district who is doing the same thing.”

(Carers)

Some carers highlighted the importance of mentally stimulating activities for people with dementia and prioritised their day tasks to fit in the iCST intervention.

“Having to fit it in and knowing that we were going to do it that day...that is a key thing that the carer needs to be aware of, their input to stimulate the person is really crucial.”

(Carer)

The “dose” relationship was considered important for intervention adherence.

“...but should treat it (the intervention) like a hospital appointment, you wouldn't miss three times a week. This is the same. It's necessary and important.”

(Carer)

Some carers found the morning to be the best time for doing the sessions. Carers commented that season of the year was also seen as influencing participation in the intervention.

“It's much easier to stimulate people in the summer than it is in the winter”

(Carer)

Carers provided some suggestions on effective training for carers which should emphasise the importance of having time and being prepared.

“Carers need to be clear about this, that they can do that, you just have to make sure you've got the time, and you have to be prepared for the next occasion when you do it”.

(Carer)

6 Chapter 6: Discussion of the iCST pragmatic RCT and the qualitative study

6.1 The iCST pragmatic RCT

This study was the first multi-centre pragmatic RCT to examine the effects of carer-delivered iCST for people with dementia on carer wellbeing. A total of 356 dyads of people with mild to moderate dementia and their family carers were recruited making this study the largest in the current literature on CST-based approaches.

The RCT results show that iCST improved carers' quality of life (QoL). Carers who delivered more sessions also had reduced depressive symptoms. However, carers' physical and mental health component ratings were not significantly different between the intervention and treatment as usual groups. There were no significant differences observed in carers' mood or in their ratings of relationship quality with the person with dementia.

The qualitative study suggests that people with dementia and their carers found iCST stimulating and enjoyable but many had difficulty completing all the sessions as planned. Three main themes emerged which were the 'Concepts of mental stimulation', 'Experiencing changes in everyday life as a result of taking part in iCST' and 'Carers' adherence to the intervention', along with ten sub-themes.

6.1.1 Methodological considerations

6.1.1.1 Response rate and attrition

The conversion rate from referrals to enrolment was 27% (356 out of 1340). The most common reason for losses of referrals was dyads expressing that they did not wish to participate in the intervention. This accounted up to 22% (292 out of 1340) and 18% (240 out of 1340) participants not meeting the inclusion criteria. The uptake

rate of similar studies of psychosocial intervention in people with dementia and family carers the community varies in accordance to recruitment methods. Woods and colleagues (2012) conducted a study with a similar population, and the study conversion rate was 17% (488 out of 2908).

In this trial, the overall attrition rate was 24% at Week 26. Previous studies suggest that an overall 30% attrition rate for long-term follow-up over six months is regarded as acceptable in this population (Prick et al., 2014; Van't Leven et al., 2013). Attrition through death and illness was the most common reason for not being available for follow-up assessments (Woods et al., 2012). In this trial, overall 79% of dyads completed the assessments and 75% of dyads completed the 6-month end-point assessment with rates of attrition being higher for the intervention than the TAU group (25.5% and 21%, respectively) at Follow-Up 2.

At Follow-Up 2 participants dropping out may have introduced bias if those dropping out had a different response to the intervention or TAU conditions compared with those that completed the trial. However, there was no evidence that the demographic variables or baseline outcome scores in those who did complete the study were different from those who did not. Participant dropout and withdrawal rates were closely monitored and reported to the Clinical Trials Unit (NORTH). The sample size was increased from 306 to 356 with an attempt to offset the attrition to 15%. Despite significant efforts made to obtain outcome data, the trial may have been underpowered to detect significant differences for the primary outcome measure due to the low attrition rate and low levels of compliance in the sessions.

6.1.1.2 Randomisation

The recruitment of family carers of people with dementia proved to be very challenging. Several reasons for losses between referral and randomisation were related to carers' busy schedule, poor health, lack of confidence in engaging their relative in the intervention or their concerns related to the intervention. A small proportion of carers did not wish to take part because the intervention was too long for them. In addition, it was difficult to involve spousal carers of people with dementia in the intervention, as many of them were older people with multiple chronic diseases of their own (George & Gwyther, 1986). For example, in this study, 63% were spousal carers with a mean age of 72.8 years. The profound negative physical and emotional consequences of caregiving reported by carers of people with dementia may become a barrier for them to participate in the intervention. Some carers were not confident in engaging their relative in the intervention, due to the progressive nature of the disease. In addition, some carers did not wish to participate because they were concerned that engaging in the intervention made their relative focus more on their illness.

6.1.2 Comparison with findings from other studies

6.1.2.1 Characteristics of carers

Demographic data were collected on carer ethnicity, relationship to the person with dementia, gender, age, education and living arrangement. The sample was comparable to other recent UK based studies involving family carers but was slightly more ethnically diverse than those described in the study of reminiscence groups for people with dementia and their family carers (Woods et al., 2012).

6.1.2.2 Carer Health-related QoL

There was no statistically significant difference in the primary outcome of SF-12 Physical and Mental Health component scores for carers between the iCST and TAU groups. The results are consistent with the study of Onder and colleagues (2005) evaluating the effects of carer-delivered home-based individual Reality Orientation which found similar results. Studies suggest that the Health Survey SF-12 instrument is more suitable for the measurement of health-related utility in psychiatric populations and potentially therefore more sensitive in detecting severities of depressive symptoms. However, in assessing changes in QoL for specific interventions, the SF-12 may underestimate changes in QoL for individuals in poor health (Turner, Campbell, Peters, Wiles, & Hollinghurst, 2013). Although carers of people with dementia are often at risk of increased stress as the disease progresses (Argimon, Limon, Vila, & Cabezas, 2005), they are not classified as a depressed patient group. A lack of an effect in carers' physical and mental health may reflect a "ceiling effect" where some carers already perceived their health condition to be in "good health" (Zarit & Leitsch, 2001).

The RCT findings showed a significant improvement of HR-QoL on the EQ-5D scores for carers in the iCST group. This finding is supported by the systematic review of the effects of carer involvement in CBIs for people with dementia on carer wellbeing (Chapter 3). This may be related to the fact that although iCST was developed largely as a home-based carer-delivered individual cognitive stimulation approach, the intervention incorporated additional psycho-educational elements for carers such as communication and opportunities to increase pleasant events for both carers and people with dementia. Furthermore, this is consistent with the findings of the qualitative study where carers reported that iCST provided opportunities to understand dementia, its impact on communication and confidence for the person

with dementia, and provided opportunities to increase pleasant activities both for themselves and their relative. Therefore, interventions targeting communication between people with dementia and their carers might potentially improve general wellbeing outcomes for family carers (Moon & Adams, 2013).

Since both the health status SF-12 and EQ-5D are widely used to evaluate HR-QoL, the contrasting findings may be due to inherent differences in the measures, or their sensitivity to specific patient groups. The EQ-5D measure may be more strongly correlated with broader measures of QoL.

6.1.2.3 Carer anxiety and depressive symptoms

In this trial, results showed no significant improvements in carers' depressive and anxiety symptoms. This finding is inconsistent to the systematic review of carer involvement in CBIs for people with dementia (see Chapter 3). Despite the fact that carers of people with dementia frequently report experiencing high levels of stress which can be detrimental to their own physical and psychological health (Garcia-Alberca et al., 2012), not all aspects of dementia caregiving are associated with decreasing health and psychological morbidity (Harmell, Chattillion, Roepke, & Mausbach, 2011). In this trial, carers did not report elevated levels of either anxiety or depression at baseline, so the possibilities for demonstrating improvement were potentially limited (Zarit & Leitsch, 2001).

6.1.2.4 The quality of the caregiving relationship

The quantitative analysis showed no effects of iCST on carers' ratings of relationship quality with the person with dementia. This result is consistent with the systematic review (chapter 2). However, in the qualitative study, carers reported that doing the iCST sessions with their relative gave them the opportunity to interact and brought

them 'closer' (Townsend 1995). These findings suggest that for some carers having 'closeness' in the caregiving relationship may have hindered an improvement in the quality of the caregiving relationship by being too emotionally demanding (Chesla, Martinson, & Muwaswes, 1994). It also suggests that lower psychological wellbeing in carers may increase negative experiences associated with the caring role, and is likely to be related to responses of frustration or withdrawal, causing further decrease in the quality of the relationship or limited improvement (de Vugt et al., 2003; Fauth et al., 2012). However, the binding ties theory suggests carers face challenges, losses and changes in their caring role, but the impact of these could be reduced by experiencing a positive caregiving relationship (Townsend et al., 1998). In addition, even when care demands are high, if carers experience less caregiving conflicts, their role strain may decrease and act as a protective mechanism in term of carers' wellbeing (Wang, Shyu, Tsai, Yang, & Yao, 2013).

6.1.2.5 Carers' adherence to the intervention

A. Carer adherence to implementing the intervention

Carer adherence data were collected and analysed to compare the differences between the set-up visit, MV1 and MV2. The findings show that carers perceived that their knowledge of iCST was improved at MV2 in comparison to the set-up visit. In addition, their confidence in delivering iCST increased at MV2 when compared with MV1. Most carers reported that they were able to 'focus on opinions rather than facts', 'develop ideas in a sensitive manner', 'incorporate their relative's personal interests in the activities', and 'adapt the sessions to accommodate their relative's abilities during the sessions. Their ratings of using the techniques and skills in delivering the sessions improved significantly at MV2 in comparison to MV1. However, from the carers' perspective there were no significant improvements in MV2 in comparison to MV1 regarding levels of engagement in the sessions with the

person with dementia. This finding is consistent with the qualitative findings reporting that the progressive nature of dementia, poor health of the person with dementia and difficulties engaging in the sessions might have hindered intervention adherence (chapter 6).

The use of self-rating questionnaires at the set-up visit, MV1 and MV2 provided carers with opportunities to reflect on their confidence, engagement, and adaptation of techniques and skills in delivering the sessions. Assessment of treatment integrity plays an important role in testing whether the intervention was carried out as intended (Perepletchikova, 2007). Although carers' adherence to the intervention shows significant improvement during the course of intervention, most people received fewer iCST sessions than the recommended numbers.

B. Carer support

Most carers valued the support they received from unblind researchers and rated this as good or excellent. Carers' satisfaction in terms of the support received from unblind researchers improved significantly at MV2 compared to MV1. This finding was supported by the qualitative study data. In the interviews, carers reported that the set-up visit training, the telephone support, and monitoring visits throughout the intervention were useful. The flexibility of telephone support was well received especially by carers who were in full-time or part-time employment.

6.2 The iCST qualitative study

6.2.1 People with dementia and carers' concepts of mental stimulation

6.2.1.1 Effects of mentally stimulating activities

Both people with dementia and their carers emphasised the importance of mental stimulation. They perceived mental stimulation as an activity that provided them with

opportunities to '*keep the brain going*', '*think*', '*reflect*', '*stay alert*' and access '*social contact*'. In the interviews, people with dementia spoke about mentally stimulating activities as the means of being motivated to engage in daily activities. Carers thought that being actively engaged in mentally stimulating activities gave the person with dementia opportunities to learn new information and look at things in "a different way" (Roland & Chappell, 2015).

6.2.1.2 Types of mentally stimulating activities

Both people with dementia and their carers provided examples of a broad range of mentally stimulating activities which centred around communication, recreation, physical, practical and social participation. They reported that getting involved in mentally stimulating activities enabled them to continue to interact with family, friends and the wider community (Roland & Chappell, 2015b).

6.2.2 Experiencing changes in everyday life as a result of taking part in iCST

6.2.2.1 Opportunities for mental stimulation

The qualitative findings suggest that taking part in iCST provided opportunities for promoting both general and intellectual stimulation. People with dementia mentioned that iCST helped them to 'think better' and to increase their alertness and awareness (Onder et al., 2005; Spector, Gardner, & Orrell, 2011). However, this finding is inconsistent with the RCT results that showed that there were no significant improvements in cognition for people with dementia.

In line with previous studies, some people with dementia reported that taking part in iCST motivated them to be mentally active. They talked about their memory "not being completely lost" (Moebs, Gee, Miyahara, Paton, & Croucher, 2015; Thomas &

Velthouse, 1990) and that they were 'fighting back' as much as they could to remain mentally active (Clare, 2002; Genoe & Dupuis, 2014).

6.2.2.2 Opportunities to communicate

People with dementia are at risk of losing communication skills as the disease progresses and may become reluctant to be involved in activities. The iCST sessions provided opportunities to communicate and share mentally stimulating activities with carers (Cartwright et al., 1994). People with dementia and family carers valued iCST as a tool which enabled them to initiate conversations, and provide a framework for communication (Onder et al., 2005).

Communication was described as playing a major role in helping carers to understand the needs of people with dementia. Carers found iCST provided opportunities for communication, engaging their relative in discussions and encouraging them to take part. Furthermore, engaging in iCST helped carers to "break" from routine care tasks and build rapport with their relative through sharing of meaningful activities (Roland & Chappell, 2015b).

6.2.2.3 Enjoyment and pleasant activities

The qualitative data indicate that the majority of people with dementia and their carers found iCST offered opportunities to be involved in enjoyable and pleasant activities. The findings highlight the importance of taking part in enjoyable activities, so that people with dementia remain engaged (Cartwright, Archbold, Stewart, & Limandri, 1994; Hellström, Nolan, & Lundh, 2007; Vance et al., 2008). The results are consistent with the enrichment process theory, whereby although the person with dementia did not remember details of the activities, they reflected on "feelings of enjoyment" and "feeling good" (Cartwright et al., 1994; Nygard 2006).

Carers described that their involvement in iCST alongside their relative was a “source” of pleasure and feelings of fulfilment. This is in contrast with the study by Milders and colleagues (2013) who examined the effects of carer-delivered cognitive stimulation and found that carer involvement in the intervention increased carers’ burden. Their findings may be related to the fact that carers often prioritise caregiving over leisure activities (Romero-Moreno et al., 2014).

6.2.2.4 Being active in everyday life

The results suggest that people with dementia and their carers valued being active in their everyday life. People with dementia mentioned that taking part in iCST motivated them to revisit and focus on new interests and hobbies. Carers also experienced changes in their everyday life such as having ‘more of a focus’ or looking for further information related to mentally stimulating activities for their relative. Carer involvement in the intervention gave them a break from routine care tasks and provided opportunities to focus on mutual sharing of pleasurable and mentally stimulating activities with their relative (Roland & Chappell, 2015b).

6.2.2.5 Brought the carer and the person with dementia ‘together’

In the interviews, most carers and people with dementia reported they were in a ‘good relationship’ prior to the sessions. However, participating in iCST provided the person with dementia and their carer with opportunities to share pleasurable and enjoyable activities which brought them ‘closer’. This finding is consistent with the RCT results which showed significant improvements on the warmth and criticism subscale of the QCPR (Spruytte et al., 2002), as rated by the person with dementia.

The qualitative findings provide further information on how people with dementia and their carers “worked” together to build a ‘closer’ relationship. People with dementia

described that iCST helped them to see ‘another side’ of their carer and enjoyed their time together. These views suggest that increased closeness can strengthen relationship quality. Participating in iCST provided them with opportunities to communicate and share pleasurable activities with their carers and to experience feelings of self-worth. This may be related to the iCST key principles helping carers to focus on the strengths of the person with dementia as opposed to limitations.

6.2.2.6 Carer’s awareness of the ‘needs’ of the person with dementia

The qualitative study showed that iCST provided carers with opportunities to interact with their relative which raised awareness of dementia as a disease. Some carers found that iCST enabled them to gain a better understanding of the cognitive needs of their relative in everyday life. This result is consistent with the scaffolding theory, which asserts that cognitive support helps carers to be sensitive to the cognitive needs of the person with dementia (Cavanaugh et al., 1989). Carers’ cognitive support may help the person with dementia to improve their abilities and achieve their goals which may increase carers’ sense of hope. Therefore, it may have contributed to the findings of the RCT of increased wellbeing in carers (Fauth et al., 2012; Genoe et al., 2010; Phinney, 2006; Townsend & Franks, 1995).

6.2.3 Carers’ adherence to the intervention

6.2.3.1 Barriers to implementing the intervention

Several barriers in taking part in iCST were identified by carers in the qualitative study. Carers found it hard to fit iCST into a busy schedule. This might relate to some carers having little time or energy for mentally stimulating activities (Adams, 2008; Campbell et al., 2008).

Some carers found it difficult to engage people with dementia in the iCST intervention because of the progressive nature of the illness (Schulz, O'Brien, Bookwala, & Fleissner, 1995). In addition, the person with dementia having poor physical health and experiencing low mood was considered as an important barrier in taking part in the mentally stimulating activities (Choi & Twamley, 2013). Challenges related to the techniques and skills in delivering the intervention were reported in some cases where carers struggled for example to apply the iCST principles. Hence, it was hard to pursue conversations and engage people with dementia in the sessions. These challenges could negatively impact on intervention adherence (Chee, Gitlin, Dennis, & Hauck, 2007). Changing roles in the caregiving relationship could become a barrier to implementing the iCST sessions. Feedback from unblind researchers suggested that in some cases, carers reported a reversal of role in delivering iCST that may have increased the strain on the caregiving relationship and acted as a barrier in completing the sessions (Quinn, Clare, Pearce, & van Dijkhuizen, 2008).

6.2.3.2 Factors increasing intervention adherence

Carers suggested that having other people help to deliver the intervention such as involving other family members supporting them may have been helpful. Carers were aware of the importance of their input in supporting the person to engage in iCST, so they stated it was crucial to prioritise their day tasks to fit in the iCST sessions. These findings imply that having a better understanding of the disease and their role prior to learning specific strategies to deliver the intervention may have enhanced adherence (Chee, Gitlin, Dennis, & Hauck, 2007).

To conclude, the overall experiences of participating in iCST were described by people with dementia and their carers as having opportunities to engage in enjoyable mentally stimulating activities, motivation to stay active and bringing people with

dementia and their carers 'together'. Carers noticed people with dementia being more alert and focused in their everyday conversations and activities after participating in iCST. This finding is consistent with the studies by Spector, Gardner, & Orrell (2011) and Brataas, Bjrgan, Wille, & Hellzen (2010). Carers reported that experiencing increased alertness motivated people with dementia to focus on new interests and revisit past hobbies. This also suggests that participating in iCST provided people with dementia with opportunities to be more attentive to the surrounding environment and engage in pleasurable and mentally stimulating activities such as going to a museum, or looking for new materials to enhance their current activities. Some people with dementia revisited past hobbies such as painting or participating in daily activities such as preparing or assisting in cooking meals. Staying 'alert' and having 'a focus' may have been seen by people with dementia and their carers as an opportunity to maintain daily skills and generally remain 'engaged' in everyday activities. From a clinical perspective, iCST may be a useful tool to help people with dementia and their carers to communicate and enhance the quality of the caregiving relationship.

6.3 Limitations

The sample of the RCT predominantly comprised of white dyads of people with dementia and their family carers. Therefore, findings might not be generalisable to other Black Minority Ethnicity (BME) groups, and overall, the sample lacked ethnic diversity. The recruitment of BME participants into dementia research poses challenges. There are several possible reasons why people from BME group are reluctant to participate in research. This may relate to cultural differences, 'social stigma' of dementia deterring people to take part, a concern of confidentiality, lack of knowledge of research in dementia or language difficulties (Moriarty, Sharif, & Robinson, 2011; Rugkasa & Canvin, 2011). It is crucial that future studies identify

barriers to research for these groups and build further relationships between community and academic sectors in order to engage BME participants (Aguirre, et al., 2014). It is essential to ensure research participation is accessible to all groups of society, regardless of ethnic and socioeconomic background (Eide & Allen, 2005; McLean & Campbell, 2003; Rugkasa & Canvin, 2011).

The recruitment to the qualitative study has several limitations. The data was collected from a convenience subsample, with was biased because most participants interviewed had done well with the intervention. Experiences of dyads that did not complete any sessions or those reporting poor compliance were not explored. This could have influenced external validity by not approaching dyads who did not complete any sessions or reported poor compliance (i.e. ten sessions or less) (Prick, de lange, Van't Leven, & Pot, 2014). Therefore, the sample is unlikely to be representative of the population being studied. The data may have been affected by social desirability bias such as carers pleasing the researcher and talking positively about the intervention.

Although carers were provided with a standardised iCST manual, the Carer Diaries, and carer set-up visits, training and support, carer adherence to the intervention and overall compliance rates were low. This might relate to a combination of the intervention being time consuming and dyads being given the flexibility to fit in sessions when possible. Most carers indicated they needed little and no support from unblind researchers. However, in some cases, carers found the frequency of the scheduled monitoring visits was insufficient for them. Therefore, a more intensive and structured support system may have provided carers with opportunities to engage with unblind researchers more often.

Although significant efforts were made to obtain outcome data, the trial may have been underpowered to detect significant differences for the primary outcome measure due to high attrition rate and low levels of compliance in the sessions. Nevertheless, this is the largest RCT of a cognitive stimulation intervention in which carers led the sessions which shows no effect on cognition and quality of life for people with dementia compared with usual care.

A high proportion of people with dementia and carers expressed interest in the intervention. Carers' self-ratings of their confidence and skills of delivering iCST were high. However, compliance was low overall. This finding may be explained in terms of carers potentially overestimating their confidence in delivering the sessions. In addition, compliance data indicate that cognitive stimulation interventions delivered by carers may be hard to put into practice, which limits the wider applicability and generalisability of these approaches.

6.4 Theoretical implications

The findings of the systematic review, the iCST pragmatic RCT and the qualitative study have contributed to the development of a theoretical framework of carer involvement in CBIs and effects on carer wellbeing. This theoretical framework is derived from the SPM of Pearlin et al., (1990) to accommodate three mediators which comprises; a) dyadic interpersonal interactions in the caregiving relationship, b) opportunities to engage in pleasurable and meaningful activities and c) cognitive support provided by carers. These mediators are interrelated and focus on positive aspects of carer involvement in CBIs (Figure 2.3).

The systematic review supports this theoretical framework and demonstrates that carer involvement in CBIs is associated with increased carer wellbeing and a

reduction of depressive symptoms. The findings of the iCST RCT showed that carer involvement in iCST for people with dementia significantly improved carer QoL. The qualitative data helped to understand people with dementia and their carers' experiences and perspectives of taking part in iCST. It also highlighted the potential mechanisms whereby carers delivering iCST experienced increases in their QoL and ratings of relationship quality by people with dementia. These mechanisms included having opportunities to engage in enjoyable and mentally stimulating activities, motivation to stay active and bringing people with dementia and their carers 'together'. The findings are in line with the theoretical model proposed and suggest that having pleasurable and meaningful experiences and taking part in mentally stimulating activities may promote carer wellbeing.

The positive aspects of dementia caregiving focusing on positive experiences for carers represent a growing field of interest. These perspectives provide a new and positively-focused approach to research in dementia caregiving highlighting the dyadic caregiving process and how this may change or be influenced by psychosocial interventions. Particularly, my PhD research proposes a framework for a better understanding of carer involvement in iCST and CBIs in which carers are involved and participate alongside their relative. This framework highlights that carer involvement may be associated with effects on both the person with dementia and the carer. It represents a new step in recognising the importance of dyadic interpersonal interactions within psychosocial interventions, and how sharing mutual pleasurable and meaningful experiences, mentally stimulating activities, and cognitive support by 'staying together' in CBIs may potentially improve outcomes for both the person with dementia and their carers. However, although effects on QoL for carers involved in CBIs may be observed, not all carers will experience these

effects, as enhanced 'closeness' in the caregiving relationship may be too emotionally demanding for some carers (Chesla, Martinson, & Muwaswes, 1994).

Finally, this work postulates that the various components of the theoretical framework are interrelated and aid in conceptualising carer involvement in dyadic CBIs and understanding the effects on carer wellbeing and the quality of the caregiving relationship. Thus, carer wellbeing and involvement continuity may contribute to positive outcomes in dementia caregiving and how people with dementia and their carers experience the caregiving relationship. This framework could be useful in developing interventions to support, enhance and maintain carer involvement. More research is needed to further validate this theoretical framework.

6.5 Future research

Despite some limitations, this PhD makes a valuable contribution to the understanding of carer-delivered CBIs for people with dementia and their effects on carers' wellbeing. Given that time remains the most important barrier for family carers to be involved in the intervention, and some people with dementia were not fully engaged in iCST, the trial should be replicated with enhanced processes to support better adherence or by introducing paid carers facilitating the intervention. Future research should consider using paid carers or other healthcare professionals to deliver the intervention which may be more feasible. However, since the trial findings show that carers delivering iCST for people with dementia improved carer HR-QoL and enhanced the quality of the caregiving relationship from the person with dementia's perspective, it is important to involve family carers whenever possible. Therefore, using paid carers and healthcare professionals as a supplement or in a supporting role in some of the sessions should be explored further, as this may increase adherence and alleviate burden on family carers.

Furthermore, the qualitative data show that most people with dementia and their carers enjoyed the sessions. However, people with dementia described the iCST sessions as not challenging enough, indicating that the design of the intervention may not meet a broad range of cognitive needs for people with dementia. A flexible telephone support system was designed to support carers, but issues of finding time to fit in the intervention were not systematically addressed. A few carers suggested increasing the frequency of monitoring visits and the need to better explain the purpose of the intervention. Therefore, future studies should consider the cognitive needs of the person at different stages of dementia, and address needs in terms of increasing support for carers. Interventions should provide carers with a better understanding of the disease and skills-based training prior to interventions. The need to find effective ways of supporting family carers to deliver the intervention is essential. It is crucial to ensure that any training provided is effective in producing the required type and quality of interactions (National Collaborating Centre for Mental Health 2007). This PhD therefore has contributed key information in terms of development of psychosocial interventions in dementia and especially those that involve carers.

Furthermore, it is important that future studies evaluate further the effects of individual cognitive stimulation interventions. This work will help to ensure the reliability and robustness of the effects reported in this study, in relation to benefits of relationship quality for people with dementia and HR-QoL for carers. Future research should involve both people with dementia and carers in the development of interventions where possible.

6.6 Implications for health care

Improvements on the carer–patient relationship and carers' HR-QoL suggest that iCST may have a major role in improving communication for people with dementia and their carers. The iCST intervention might also be useful in care homes for residents since the intervention provides opportunities for both people with dementia and their carer to interact and share mentally stimulating activities.

The qualitative evidence showed some people with dementia did not remember details of the activities, but they could reflect on feelings of enjoyment. It is important to be aware of the feelings of people with dementia and how enjoyable shared activities may enhance the quality of the caregiving relationship (DiLauro, Pereira, Carr, Chiu, & Wesson, 2015). The findings also suggest that clinicians who support cognitive stimulation activities for people with dementia may choose to focus on both people with dementia and their carer. The iCST intervention was primarily designed to deliver benefits for people with dementia. However, from a clinical perspective, reduction in depressive symptoms and improvement in HR-QoL for carers have important implications for clinical practitioners and policymakers so that carer outcomes are included in service delivery and service evaluation.

6.7 Conclusion

My PhD research aims were to evaluate the effects of carer-delivered iCST for people with dementia on carer wellbeing. This PhD research is unique in developing a theoretical framework of carer involvement in CBIs for people with dementia and is primarily related to interpersonal interactions, sharing pleasurable meaningful experiences, mentally stimulating activities and provision of cognitive support by carers to people with dementia. It is the first study to systematically review carer involvement in CBIs based on the theoretical framework above. This study is also

the first large multi-centre pragmatic RCT involving people with mild to moderate dementia and their carers in a carer-delivered cognitive stimulation intervention. It is innovative due to the fact that it employed a mixed methods design approach, inclusive of a qualitative study exploring the concepts of mental stimulation and the experiences of people with dementia and their carers taking part in iCST.

This research contributes further to our knowledge of dyadic CBIs for people with dementia and the effects of these types of interventions for carers. The findings support the use of enjoyable and mentally stimulating activities that people with dementia share with their carers which are associated with increased carer QoL and a reduction of depressive symptoms for those carers completing more sessions with their relative. These quantitative findings are consistent with the systematic review and are further enriched by the results of the qualitative study. For example, people with dementia and their carers felt an increased closeness to their relative when they took part in iCST, indicating that iCST may be a useful tool to encourage carers and people with dementia to communicate and engage in stimulating activities. The qualitative findings also showed that taking part in cognitive stimulation activities motivated the person with dementia to stay mentally active and maintain past activities or engage in new ones. iCST was described by carers as an intervention that provided opportunities for carers to 'stay together' and understand their relative's cognitive needs. Carers' awareness of people with dementias' cognitive needs may have further enhanced the patient and carer relationship.

Both the quantitative and qualitative findings are in line with the theoretical framework of carer involvement in CBIs for people with dementia (Figure 2.3). In line with this framework, the results support the notion that carer involvement conceptualised as opportunities for mutual sharing of meaningful experiences,

mentally stimulating activities and cognitive support by carers is associated with increased carer wellbeing. This suggests that iCST has a range of benefits for family carers and so policy makers and providers should consider how these types of interventions can be disseminated and implemented in practice.

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STUDY PROTOCOL

Open Access

Individual Cognitive Stimulation Therapy for dementia (iCST): study protocol for a randomized controlled trial

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Abstract

Background: Improving the quality of care for people with dementia and their carers has become a national priority in many countries. Cognitive Stimulation Therapy (CST) groups can be beneficial in improving cognition and quality of life for people with dementia. The aim of the current study is to develop and evaluate a home-based individual Cognitive Stimulation Therapy (iCST) programme for people with dementia which can be delivered by their family carer.

Methods: This multi-centre, pragmatic randomised controlled trial (RCT) will compare the effectiveness and cost-effectiveness of iCST for people with dementia with a treatment as usual control group. The intervention consists of iCST sessions delivered by a carer for 30 minutes, 3 times a week over 25 weeks. For people with dementia the primary outcome measures are cognition assessed by the ADAS-Cog, and quality of life assessed by QoL-AD. For carers, quality of life using the SF-12 is the primary outcome measure. Using a 5% significance level, comparison of 306 participants will yield 80% power to detect an effect size of 0.35 for cognition as measured by the ADAS-Cog, and quality of life as measured by the QoL-AD. Quality of life for the carer will be measured using the SF-12. The trial will include a cost-effectiveness analysis from a public sector perspective.

Discussion: The UK Department of Health has recently stressed that improving access to psychological therapies is a national priority, but many people with dementia are unable to access psychological interventions. The development of a home-based individual version of CST will provide an easy to use, widely available therapy package that will be evaluated for effectiveness and cost-effectiveness in a multi centre RCT.

Background

Caring for people with dementia has an enormous impact on health and social care services and on family carers [1]. The cost of dementia in the UK is over £17 billion a year [2]. With the number of people living with dementia expected to double in the next thirty years, improving the quality of care for people with dementia and their carers has become a national priority [1]. In the UK there is growing recognition that psychological therapies for dementia should be more widely available. Indeed the National Service Framework for Older People emphasises the use of non-pharmacological management strategies, such as mental stimulation for dementia, and

the UK Department of Health has identified improving access to psychological therapies as a priority [3].

Cognitive Stimulation Therapy (CST) is an evidence-based approach for people with dementia developed following Cochrane reviews of several psychosocial therapies for dementia, primarily reality orientation (RO) [4]. RO involves the presentation and repetition of orientation information, such as the date, day and weather [5]. This may take place intensively throughout the day, or in regular structured group meetings. Benefits of RO noted in the Cochrane review [4] included improved behaviour and cognition. In addition the need for a more detailed and ongoing programme of orientation activities and large scale multi-centre trials to evaluate this approach was identified. Spector *et al.* found that participating in CST improved quality of life and cognition for people with

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dementia [5]. CST may also be more cost-effective than anti-dementia drug treatments [6]. CST is currently the only non-pharmacological therapy recommended by the National Institute for Health and Clinical Excellence (NICE) guidelines [7] to improve cognition in people with mild to moderate dementia. A pilot study of an extended programme of maintenance CST found a significant improvement in cognitive function for those receiving maintenance CST, suggesting that benefits could be maintained by weekly sessions for at least 6 months [8]. Olazaran *et al.* also found that CST groups had long-term cognitive benefits for people with dementia [9]. The Maintenance CST programme (comprising 14 CST sessions over 7 weeks plus an additional 24 weekly maintenance CST sessions) and accompanying manual have now been further developed as part of the SHIELD study [10] and evaluated in a randomised controlled trial (RCT). The results of the Maintenance CST trial are expected soon.

The use of group CST is growing rapidly in the UK and internationally, yet many people with dementia may be unable or unwilling to participate in group CST. This could be because they do not want to go out, or because they have restricted mobility or health issues that prevent them from getting out; they may choose not to participate in group-based activities, or groups may not be running in their local area. To assess the acceptability of an individualised CST programme we surveyed care staff attending CST training sessions and carers from the charity *For Dementia*, and we spoke to carers and people with dementia. There was a consensus from people with dementia and family carers that individualised CST should be a high priority because it was likely to be very useful. Comments included 'sounds terrific', 'could bring the carer and person with dementia closer together', 'good for people who won't go out', and 'definitely needed as a useful alternative to medication'. Taken together the evidence suggests that a large-scale trial of iCST for dementia in the UK is feasible, likely to be effective and should be a high priority for research.

Few studies have focused on the use of cognitive stimulation programmes in the home environment. In a pilot study, Moniz-Cook *et al.* [11] found that a home-based memory management programme involving the family carer led to improvements in memory in the person with dementia, improvements in carer wellbeing, and a reduction in care home admissions at 18 months follow-up. Similar benefits in cognition in people with dementia and carer wellbeing have been reported in studies by Quayhagen *et al.* [12] and Quayhagen and Quayhagen [13]. Onder *et al.* [14] carried out a study of patients with Alzheimer's disease (AD) taking cholinesterase inhibitors. The intervention consisted of a standardised programme of RO delivered by the family carer in the home for 30 minutes, three times a week over 25

weeks. Alongside training, carers were given a manual, specific schedules for each session, and guidance on how to deliver the sessions. The experimental group receiving the intervention improved relative to the control group on both the Mini Mental State Examination (MMSE) and the Alzheimer's Disease Assessment Scale – Cognitive subscale (ADAS-Cog).

The primary aim of the proposed trial is to investigate whether individual home-based CST benefits cognition and quality of life in people with dementia and improves carer well-being. Based on previous research findings, we hypothesize that people with dementia receiving iCST will show improvements in cognition and quality of life. A secondary aim of the trial is to explore the costs of those receiving iCST compared to a control group, and to investigate whether iCST is cost-effective.

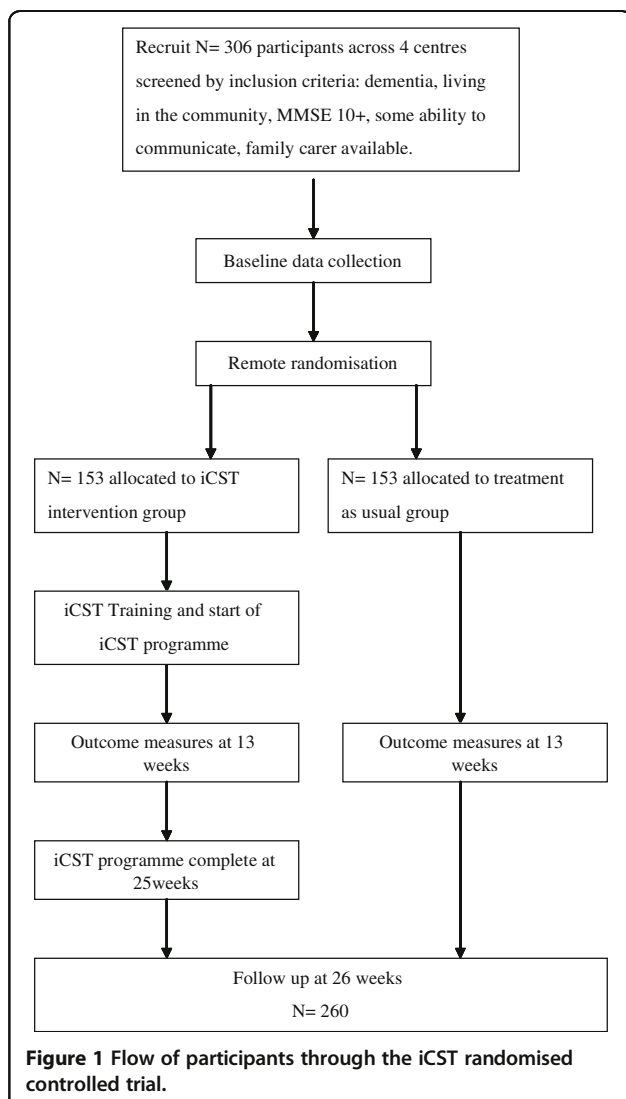
Methods

Design

The design is a multi-centre, single blind, randomized, two-treatment arm (iCST over 25 weeks vs. treatment as usual, or TAU), controlled clinical trial (Figure 1). After recruitment and baseline assessments, pairs of people with dementia and their carer are randomly allocated into either the treatment group (receiving three 30-minute weekly sessions of iCST delivered by the carer for 25 weeks) or control group (receiving treatment as usual for 25 weeks). Primary and secondary measures are completed at baseline (T0) before the iCST programme, first follow-up at 13 weeks after baseline (T1) and second follow-up and primary endpoint at 26 weeks after baseline (T2).

Sample size

Cognition (ADAS-Cog) will be the primary outcome measure. The group CST study by Spector *et al.* [5] had an effect size (standardised mean difference, or SMD) of 0.32. The Spector *et al.* Cochrane Review of RO [4] found an SMD of 0.58. The Maintenance group CST study [8] found an SMD of 0.68 compared to TAU. A recent Cochrane Review of cognitive stimulation found an SMD of 0.37 [15]. Taking a conservative estimate, SMD relative to TAU for iCST is estimated to be at least 0.35. In order to detect an SMD for iCST of 0.35 on the ADAS-Cog with 80% power at a 0.05 (two-sided) significance level, and assuming 15% attrition, a sample size of 306 people with dementia will be required. Experience in previous trials including the CST trial, the needs in care homes trial [16], and the activities in care homes trial [17], indicates a 12 to 15% loss to follow-up (7 to 10% excluding deaths) is likely. To safeguard loss to follow-up, standard procedures to maximize the follow-up sample will be applied. These will include regular contact with carers via telephone, letters (for example, reminders for assessment



or training appointments) and email, if requested by the carer.

Participants

Recruitment to this trial will take place in a variety of community settings including community mental health teams for older people (Chats), memory clinics, outpatient clinics, day centres and voluntary sector organisations such as Age Concern and the Alzheimer's Society. Some participants in both the intervention and TAU groups will be taking anticholinesterase inhibitors; in these cases participants will continue taking them throughout the study. Participants will be screened for eligibility using the Spector *et al.* [4] standardised criteria for psychological treatment of people with dementia. Participants must meet the Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV criteria for dementia, have dementia of mild to moderate severity (MMSE

≥10), have some ability to communicate and understand, and be able to see and hear well enough to participate in activities. In addition, they must have a carer who will be available to deliver the intervention, live in the community, and have no major illness which could affect participation. Participants may only enter the study after giving informed consent in accordance with the provisions of the Mental Capacity Act 2005 [18].

Randomisation

Randomisation will occur after screening and baseline assessments. The allocation ratio for randomisation is 1:1, into either the intervention group or control group (TAU). Participants will be stratified by centre (London, Bangor, Hull or Manchester) and whether they are taking anticholinesterase inhibitors, to ensure even distribution of the sample between the treatment and control groups. Registered participants will be randomised by the web-based randomisation service managed by North Wales Organisation for Randomised Trials in Health (NORTH), an accredited UK Clinical Trials Unit. The randomisation algorithm is a dynamic adaptive method that ensures balance overall, within each stratification variable and within each stratum. This allows sequential randomisation of participants, minimising selection bias while maintaining an acceptable level of balance [19]. Although participants cannot be blinded to their treatment allocation, researchers carrying out follow-up assessments will be blinded to the treatment condition. Our experience shared by similar projects is that participants may occasionally inadvertently reveal their allocation to researchers. In order to reduce this effect, participants will be given explicit reminders before the experimental visit and self-reported measures will be used wherever feasible. Assessors will record their impression of which arm of the trial each participant belongs to, and their confidence in that prediction. This will enable us to conduct a retrospective estimation of the integrity of blinding, to test whether inadvertent loss of blinding leads to bias, and to adjust for any bias detected.

Intervention

The iCST programme is based on a modified CST manual, the recent Cochrane review of cognitive stimulation [15], Onder's programme [14] and consultation with carers and people with dementia. iCST will be delivered by a carer in regular contact with the person with dementia for 30 minutes, three times a week over 25 weeks. The iCST programme comprises 75 iCST sessions consisting of structured cognitive stimulation through themed activities (for example, number games, associated words) (Table 1) tailored to the ability, interests and needs of the individual. Carers will receive the

Table 1 Individual cognitive stimulation therapy (iCST) themes

iCST Session theme	Session number
My life	1, 2, 45, 46
Current affairs	3, 4, 57, 58
Food	5, 6, 55, 56
Being creative	7, 8, 63, 64
Number games	9, 10, 71, 72
Quiz games	11, 12, 75
Sounds	13, 14, 51, 52
Physical games	15, 16, 49, 50
Categorizing objects	17, 18, 65, 66
Household treasures	19, 20
Useful tips	21, 22, 47, 48
Thinking cards	23, 24
Visual clips discussion	25, 26
Art discussion	27, 28, 43, 44
Faces/scenes	29, 30, 59, 60
Word games	31, 32, 41, 42, 73, 74
Slogans	33, 34
Associated words/discussion	35, 36, 61, 62
Orientation	37, 38, 67, 68
Using money	39, 40, 69, 70
Childhood	53, 54

iCST instructional Manual and Activity Workbook for use during the programme. The Manual provides guidance on how to run the sessions, the key principles of iCST and ideas for activities for each session. The Activity Workbook contains paper-based resources for activities suggested in the manual. Carers will also be provided with the iCST kit, which will include additional resources such as a deck of cards, set of dominoes, magnifying card, sound activity compact discs (CDs), set of boules, and world and UK maps. A first draft of the iCST Manual, Activity Workbook and iCST kit will be developed by the research team, and presented to people with dementia and carers in interviews and focus groups (adhering to Medical Research Council (MRC) guidance [20]). The purpose of consultation with service users is to ensure that the Manual and Activity Workbook are easy to use, describe meaningful activities, are appropriately tailored to people with mild and moderate dementia, and that the iCST kit contains suitable items. The iCST package will be further evaluated using the Delphi process of consensus methodology, in line with guidelines for consensus methods in medical and health services research [21]. A feasibility study with a sample of 20 people with dementia and their carers will be carried out prior to the main RCT. A final draft of the iCST

package incorporating findings from the feasibility study will be produced for use in the full trial.

Treatment adherence, carer training, and support

Previous research suggests that in order to investigate treatment process variables, and to ensure that psychosocial interventions can be replicated, it is necessary to have precise descriptions of treatment components, and to ensure that the treatment delivered was indeed the treatment intended. We will follow previous studies [22] applying the treatment integrity model, developed and expanded by Lichstein, Riedel and Grieve [23]. Carers will receive standardised training either in their homes or in a group setting, according to which is most convenient for the carer. The training that researchers will provide to carers will focus on how to use the iCST Manual and Activity Workbook, implementing the key principles of CST and problem solving strategies. In the training session the researcher will show clips of good practice in CST from the *Making a Difference 2* training digital video disc (DVD). The DVD was developed as part of the Maintenance CST trial [10]. If the training session is home-based, the carer will be invited to deliver the first session with support from the researcher, who will provide assistance and feedback. Carers will receive the iCST Manual, Activity Workbook and kit as part of a training and set-up visit. Researchers will be guided by a standardised treatment protocol detailing training procedures and support provided. During the trial carers will receive up to ten hours of support over six months, including telephone support (initially weekly) and two visits from the unblinded researcher. In the event that the family carer is unable to continue delivering iCST, another appropriate carer can be substituted.

Usual care

The control group will receive TAU, which may vary between and within centres and change over time, therefore the study will evaluate the additional effects of iCST. In terms of treatment we would expect most people with mild to moderate AD will either be on, or have been considered for, cholinesterase inhibitor medication. The Client Service Receipt Inventory (CSRI) will enable us to accurately record use of drugs and services across the two groups and any changes that occur. In general, the services offered to this group will also be available to those in the active treatment group, so we will be examining the additional effects of iCST.

Resource use

The CSRI [24] will allow us to record the utilisation of services and the interventions received during the study, and the support provided by carers, as well as the use of cholinesterase inhibitors and other psychiatric medications

such as antipsychotics and antidepressants. Data will also be collected on the inputs required to deliver the intervention.

Ethical approval

Ethical approval was obtained through the Multi-centre Research Ethics Committee (ref no.10/H0701/71), and the study is registered as a clinical trial (ISRCTN 65945963). There appear to be no documented harmful side effects from participating in CST groups, and no serious adverse reactions were apparent in the CST study [5]. Prospective participants will be fully informed of the potential risks and benefits of the project. A reporting procedure will be in place to ensure that any serious adverse events are reported to the Chief Investigator. Participants will be in the mild to moderate stages of dementia, and would therefore generally be expected to be competent to give informed consent for participation, provided that appropriate care is taken to explain the research. Where the participant's level of impairment increases, so that he/she is no longer able to provide informed consent, the provisions of the Mental Capacity Act [18] will be followed, with the family caregiver as a consultee.

Outcome measures

Primary outcome measures for the person with dementia

Cognition will be measured using the ADAS-Cog [25], which consists of 11 tasks assessing disturbances of memory, language, praxis, attention and other cognitive abilities, referred to as the core symptoms of AD, with good reliability and validity [26]. Quality of life will be measured using the Quality of Life Alzheimer's disease Scale (QoL-AD) [27] which consists of 13 domains of quality of life. The measure is recommended by the European consensus on outcome measures for psychosocial interventions in dementia [28].

Secondary outcome measures for the person with dementia

Quality of life will also be measured with the Dementia Quality of Life (DEM-QOL) scale [29]. The scale uses self-rated reports of quality of life across five domains administered to the person with dementia by a trained interviewer. It has high internal consistency, acceptable inter-rater reliability and good concurrent validity, with moderate associations with the QoL-AD [30]. It is included as a quality of life scale and a utility measure since an algorithm is now available to convert the DEM-QOL and DEM-QOL-proxy into utility scores [31]. Behaviour will be assessed using the Neuropsychiatric Inventory (NPI) [32]. The NPI measures 10 behavioural disturbances occurring in dementia patients. It is reported to be both valid and reliable [33]. Functional ability of the person with dementia will be assessed

using the Bristol Activities of Daily Living Scale (BADLS) [34], which is a carer-rated instrument assessing items rated as important by carers in 20 daily-living abilities. The measure shows sensitivity to change in people with AD taking anticholinesterase medication, and is associated with changes in the ADAS-Cog [35]. Depressive symptoms will be measured by the Geriatric Depression Scale (GDS-15) [36], comprising 15 easy-to-use items. The GDS-15, although principally a self-rating scale, may be used as an observer-administered scale, with acceptable sensitivity and specificity in people with mild to moderate dementia [37]. Quality of the carer-patient relationship (QCPR) [38] will be assessed by both the carer and the person with dementia. The QCPR is a measure of relationship quality, comprising 14 items designed to assess warmth, levels of conflict and criticism in the caregiving relationship. Previous studies have shown that the QCPR has good internal consistency and concurrent validity [38].

Primary outcome measures for the carer

Health-related quality of life will be measured using the Short Form-12 Health Survey (SF-12) [39]. The SF-12 is a comprehensive, psychometrically sound, and efficient measure of health which includes eight concepts commonly represented in health surveys: physical functioning, role functioning, physical pain, general health, vitality, social functioning, emotional and mental health.

Secondary outcome measures for the carer

Anxiety and depression will be assessed using the Hospital Anxiety and Depression Scale (HADS) [40], a widely used measure of self-reporting consisting of 14 questions, validated in several age groups, which identifies caseness for clinically significant depression and anxiety [41]. Self-reported health related quality of life will be measured using the EQ-5D [42]. The EQ-5D is a self completed measure yielding a simple descriptive profile and a single index value for health status. It has been used in a wide range of study populations (Pickard *et al.*, 2007 [43]; Dyer *et al.*, 2010 [44]). Resilience in carers will be measured with the Resilience Scale (RS-14) developed by Wagnild and Young [45]. In the shorter version of this scale participants are asked to respond to each item by either agreeing or disagreeing with each statement, with higher scores indicating stronger resilience. Previous studies have shown that the measure demonstrates high internal consistency and construct validity [46].

Economic measures

Care and support levels will be assessed using the CSRI [24], adapted for this study and used extensively in studies of mental health and dementia. The CSRI gathers

comprehensive data on accommodation, medication and services received, as well as details of unpaid support from carers, and wider carer economic impacts. A form for monitoring treatment adherence will be devised for this study and will include questions on the amount of time required from professionals and carers to support the delivery of the training package. Costs of care and support can be estimated from these service-use data by applying relevant, nationally generalisable unit costs, drawing on the National Health Service (NHS) reference costs [47] and the annual Personal Social Services Research Unit (PSSRU) volume [48]. The costs of delivering the training package (excluding costs of the initial development and testing of the package) will be calculated from the perspective of commissioners (NHS, local government) and also in terms of costs to carers of their time. Costs will be reported in aggregated and disaggregated form (NHS overall, local government, society as a whole) to show total programme cost, cost per participant (person with dementia), and cost per participant-carer pair. Cost effectiveness will be computed in a number of different ways as the difference in costs between the iCST and control group over the trial period, divided by the difference in outcomes (cognition, quality of life, or QALYS). See the Economic evaluation section below for details.

Analysis

An intention-to-treat analysis will be carried out, in that all available data will be included. A method of multiple imputation using a linear regression model will be used where needed for imputing missing data. The sample size calculations are based on the numbers estimated to be available at the study endpoint, 6 months after randomisation. Analysis of covariance will be used to adjust for baseline differences that may influence outcome variables. Variables to be considered in the model will include, among others, gender and age. Analyses will consider the evaluation 6 months after randomisation as the primary endpoint in evaluating the effectiveness of iCST. Further model definition will be provided in the statistical analysis plan.

Economic evaluation

The main economic evaluation will be a cost-effectiveness analysis (CEA), first from a health and social care perspective, and second, from a societal perspective. Service-use data, and information on unpaid carer support will be collected using an adapted CSRI, and then converted into estimates of costs by applying nationally generalisable unit cost data.

Carer inputs will be costed in two ways, using either a replacement cost assumption or an opportunity cost assumption (Koopmanschap, 2008 [49]; Pritchard, 2000

[50]). The primary CEA will measure effectiveness using the ADAS-Cog; further analyses will look at other outcomes, particularly quality of life as measured by the QoL-AD and QALYs generated from the DEMQOL and DEMQOL-proxy by applying societal weights [31]. The use of QALYs will allow bodies such as NICE to make recommendations about the use of health and social care resources so as to achieve the greatest impact from given budgets; cost-per-QALY calculations are increasingly used in health systems in pursuit of greater allocative efficiency (Smith and Richardson, 2005 [51]; Rawlins and Culyer, 2005 [52]). Each such CEA will be conducted from a health and social care perspective, and then from a societal perspective.

Cost-effectiveness acceptability curves will be plotted, generated from the net benefit approach and using bootstrap regression for a range of values of willingness to pay for incremental primary outcome measure changes and QALY gains. CEACs are widely employed as a way to quantify and graphically represent uncertainty in economic evaluation studies of health care technologies [53]. The economic evaluation will be fully integrated into the main outcome evaluations. Sensitivity analyses will be carried out to determine whether changes in the values of the main parameter estimates affect the results of the analyses.

Discussion

This is an innovative RCT that evaluates the effectiveness and cost-effectiveness of individual CST for people with dementia and their carers. The development of carer-led therapies could ease pressure on local services, which are in great demand but often severely limited. In 2009, the UK National Audit Office reported that CST was available in 29% of CMHTs for older people [54] and a home-based version of CST, could help people with dementia having limited access to CMHT services. By placing emphasis on working with the person with dementia and family carer together, the study meets the current demand for relationship-centered care and will provide the opportunity to explore the dynamics of carer-led therapies compared to professional-led therapies. We anticipate that actively involving carers in the delivery of a therapy package will be empowering, and will also have a positive impact on their well-being.

The NICE-Social Care Institute for Excellence (SCIE) guidelines [7] on the management of dementia offer few evidence-based recommendations on psychosocial approaches, due to a paucity of high quality RCTs. The current RCT is the first study to assess the cost-effectiveness of an individualised carer-led cognitive intervention in dementia.

The potential benefits of iCST include improved well-being for people with dementia and their carers, and

economic and social benefits such as reduced costs of care and delayed institutionalisation. iCST can also be offered in combination with anti-dementia medication, and also provides an option for those unsuitable for, or unwilling to take medication. However, the success of iCST will be heavily dependent on family carers being motivated and able to invest time to adhere to the programme. The number of commitments (for example, hospital appointments) and responsibilities (for example, household upkeep) carers have on an everyday basis, and how well they are coping with caring for their relative with dementia may have an impact on adherence to the programme. In addition, carer's confidence in their ability to adopt a therapeutic role delivering iCST sessions may also affect the success of the programme, as some may consider this to be a role best occupied by healthcare professionals and day centre staff. Providing a high quality interactive training package and adequate support for carers will be key to avoiding or minimising the impact of these potential issues.

A longer term follow up would be beneficial to examine rates of institutionalisation and cost of care in the months or years following completion of the iCST programme, to determine whether iCST plays a role in delaying institutionalisation and reducing the cost of care beyond the duration of taking part in the sessions. The trial results will contribute to future practice guidelines and, if successful, the iCST programme could be widely used across the UK and internationally, and become the gold standard for individual cognitive stimulation-based interventions in dementia.

Trial status

The trial is ongoing.

Abbreviations

AD, Alzheimer's disease; ADAS-Cog, Alzheimer's Disease Assessment Scale - Cognitive Subscale; CMHT, community mental health team; BADLS, Bristol Activities of Daily Living Scale; CEA, cost effectiveness analysis; CEAC, cost effectiveness acceptability curve; CSRI, Client Service Receipt Inventory; CST, cognitive stimulation therapy; DEMQoL, Dementia Quality of Life; DEMQoL-proxy, Dementia Quality of Life Proxy; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders; DVD, digital versatile disc; EQ-5D, European Quality of Life - 5 Dimensions; GDS, Geriatric Depression Scale; HADS, Hospital Anxiety and Depression Scale; iCST, individual cognitive stimulation therapy; maintenance CST, maintenance cognitive stimulation therapy; MMSE, Mini Mental State Examination; NHS, National Health Service; NPI, Neuropsychiatric Inventory; NICE, National Institute for Health and Clinical Excellence; NICE-SCIE, National Institute for Health and Clinical Excellence - Social Care Institute for Excellence; NWORTH, North Wales Organisation for Randomised Trials in Health; PSSRU, Personal Social Services Research Unit; QALY, quality adjusted life year; QCP, quality of the carer patient relationship; QoL-AD, Quality of Life Alzheimer's Disease; RCT, randomised controlled trial; RO, reality orientation; RS-14, Resilience Scale; SF-12, Short Form-12 Health Survey; SHIELD, Support at Home, Interventions to Enhance Life in Dementia; SMD, standardised mean difference; TAU, treatment as usual; T0, baseline; T1, first follow-up; T2, final follow-up.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MO, RTW and AS developed the original concept of the trial, and MO drafted the original protocol. IR developed the design and methodology; ZH developed the analysis plan; MK and CH developed the health economic component. LY and VO adapted the trial proposal as a protocol paper; LY, AS, MO and VO have contributed to the development of the iCST approach; all authors reviewed and commented on drafts of the protocol and paper. All authors read and approved the final manuscript.

Acknowledgements

We acknowledge the support of the National Institute for Health Research (NIHR), through the Dementias and Neurodegenerative Diseases Research Network. The grant holders are Professors Orrell (UCL), Burns (Manchester), Russell (Swansea), Woods (Bangor), Moniz-Cook (Hull), Knapp (LSE), and Spector (UCL). This article presents independent research commissioned by the NIHR under the Health Technologies Assessment Programme. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

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Received: 2 May 2012 Accepted: 10 September 2012

Published: 22 September 2012

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doi:10.1186/1745-6215-13-172

Cite this article as: Orrell et al.: Individual Cognitive Stimulation Therapy for dementia (iCST): study protocol for a randomized controlled trial. *Trials* 2012 **13**:172.



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Telephone: 020 8926 5025

Facsimile: 020 8926 5009

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24 September 2010

Professor Martin Orrell
Professor of Ageing and Mental Health
University College London
2nd Floor, Charles Bell House
67-73 Riding House Street
London
W1W 7EJ

Dear Professor Orrell

Study Title:	Individual Cognitive Stimulation Therapy for dementia (ICST Trial)
REC reference number:	10/H0701/71
Protocol number:	8

Thank you for your letter of 20 September 2010, responding to the Committee's request for further information on the above research [and submitting revised documentation].

The further information was considered by a sub-committee of the REC at a meeting held on 23rd September 2010. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter		20 September 2010
Participant Information Sheet	9	14 September 2010
Participant Consent Form: caregiver	9	20 September 2010
Response to Request for Further Information	1	20 September 2010
Participant Information Sheet: Home caregivers	9	14 September 2010
Participant Consent Form	9	20 September 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0701/71

Please quote this number on all correspondence

Yours sincerely

Janet Carter
PP

Rev'd Dr Joyce Smith
Chair

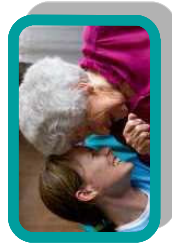
Email: janet.carter@redbridge-pct.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments [if final opinion was confirmed was given at a meeting]*

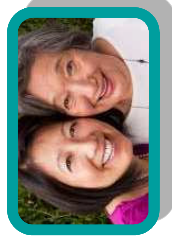
*"After ethical review – guidance for researchers"
SL- AR2 for other studies]*

Copy to: *Dr Aimee Spector
[R&D office for NHS care organisation at lead site]*

What is the iCST Programme?



The iCST study is a Health and Technology Assessment funded programme (HTA), sponsored by University College London (UCL). It aims to increase quality of life and cognition for people with dementia.



In response to the government's emphasis on improving early interventions and home care for people with dementia, we have developed a home based individual Cognition Stimulation Therapy (CST) package delivered by family carers.

What is Individual Cognitive Stimulation Therapy?

Individual Cognitive Stimulation Therapy (iCST) is based on the evidence based group CST therapy for people with mild to moderate dementia, which has been found to be beneficial for cognition and quality of life.



The individual CST programme, is delivered by a relative or close friend of the person with dementia for 30 minutes, 3 times a week, over 25 weeks.



Each individual CST session consists of a themed activity (i.e. life story, discussion of current affairs, being creative) and is designed to be mentally stimulating.



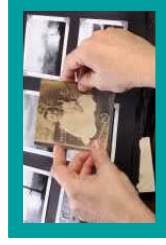
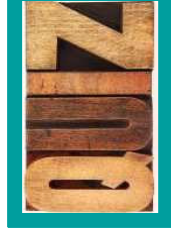
Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given an information sheet to keep and be asked to sign a consent form.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you or your relative/friend receives.

What are the possible benefits of taking part?

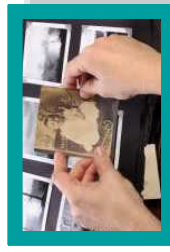
If you decide to take part, and your relative/friend is involved in iCST, we hope that this may be of some help to them. Previously, people participating in group CST have reported that they have enjoyed the experience greatly.



What will participation involve?

If you decide to take part in iCST, you and your relative will be asked to meet with a researcher for an interview, which will involve completing several questionnaires.

If you are allocated in the treatment group, you will be additionally asked to receive training, which will teach you how to deliver iCST. If you are randomized to the treatment as usual (control) group you and your relative will not receive any additional intervention.



Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you keep your appointments with us during the time that you are taking part.

If you are interested in taking part in the iCST programme

Please contact

Phuong Leung

Tel: 0207 679 9023

Mobile: 07951 519 451

Email: phuong.leung@ucl.ac.uk

For more information about the study

Dr Vasiliki Orgeta

iCST Trial Coordinator

University College London
Mental Health Science Unit
67-73 Riding House Street
2nd Floor, Charles Bell House
London W1W 7EJ

Tel: 0207 679 9294

Mobile: 07731 488 805

Fax: 0207 679 9426

Email: v.orgeta@ucl.ac.uk



The iCST study is funded
by the National Institute for Health Research's
Health Technology Assessment Programme.

UCL

iCST

Individual Cognitive Simulation Therapy

**A programme of
research to improve
quality of life and
cognition for people
with dementia**



NHS
**National Institute for
Health Research**



Date:

Name and Address of Blind Researcher
University College London
Charles Bell House
67-73 Riding House Street
W1W 7EJ
Phone:
Mobile:
Email:

Dear Mr and Mrs ,

I hope my letter finds you well and may I take this opportunity to thank you for your time and interest in our study. I am writing to you to inform you that we will be contacting you by phone within the next two weeks. The purpose of my phone call will be to arrange a time to visit you (at a time that is most suitable for you). During the visit you will be asked to complete several questionnaires. The interview process is identical to the previous one and will take approximately two hours.

All information that is collected about you during the course of the research will be kept strictly confidential. Access to this information will be limited to the research team.

May I also remind you that because of the nature of the project **it is significant that you do not communicate to me whether you have been delivering the cognitive stimulation sessions or not.**

If you would like any further information please feel free to contact me at any time. If you would not like to be further contacted about this research please phone mobile or my office number at office number.

Thank you very much for your time in reading this letter and your commitment to our project.

I am looking forward to seeing you soon.

Yours sincerely,

Name of Blind Researcher

INFORMATION SHEET FOR HOME CAREGIVERS

Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

Invitation to participate in a research study

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individualised (one-to-one) cognitive stimulation is effective in improving cognition and quality of life for the person with dementia.

What happens in individualised cognitive stimulation?

iCST sessions, lasting 30 minutes, will take place three times a week for 25 weeks. They will be delivered by yourself, and you will receive training and ongoing support to help you with this. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

Why have I been chosen?

You have been invited to take part because of your support for a person who at some point had a memory assessment. We need a large number of people with memory problems to help us evaluate iCST – 260 in total.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your relative / friend receives.

What will happen to me if I take part?

This study is a randomised trial. We need to establish the additional benefits of iCST, so we need to compare any changes experienced by people receiving treatment to other people receiving no treatment. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of receiving iCST. The decision is made by an independent computer, which will not have any identifying information about you or your relative/friend.

If you decide to take part, your participation in the study will last for a time period of six months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Meet with a researcher for between one / one-and-a-half hours to complete some questionnaires. These will concern both the person you are caring for (asking questions about their quality of life, use of services, medication, accommodation, behaviour and activities of daily living) and yourself (asking questions about your general health, mood and quality of life). The time stated to complete the interviews and questionnaires is an estimate; you and your friend/relative may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.
2. Repeat these questionnaires with the researcher after 13 weeks and then after another 13 weeks. This is to see whether any of these factors change as a result of the iCST intervention.

Usually, the researcher will come to your home or the home of your relative/friend if you live separately, but will be happy to meet you elsewhere if you would prefer. The researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

If you are allocated to deliver the iCST intervention, you will be additionally asked to:

1. Attend a training over two half-days, which will teach you how to deliver iCST. You will also be given a manual and DVD to assist you through the iCST sessions. A researcher will visit you at home before the iCST programme starts, and go through the sessions with you, helping to plan what you will be doing. This will include an appraisal of the interests and abilities of the person you are caring for, adapting the programme to suit their needs. They will also discuss the resources available at home. You will receive up to ten hours support over the six months, including telephone support (initially weekly) and three home visits. You will be asked to keep a diary, so that we have a record of what you are doing including how much you think the person is interested in and enjoying the sessions.
2. Some people will additionally be asked to be interviewed (alongside the person with dementia), to investigate the impact of iCST on the person with dementia's experience, both during the sessions and any generalised effects into everyday life, the carer role and carer relationship. Participation in this part of the study is entirely voluntary and whether or not you take part will have no impact on the rest of the study.

Expenses

Any travel expenses incurred by yourself or your relative/friend will be reimbursed.

What do I have to do?

Taking part in the study does not involve any lifestyle restrictions or changes either for you or your friend, relative. You can carry on your everyday activities as normal while participating in the study. All we ask is that you help your relative /friend to keep their appointments with us during the time that they are taking part.

What if my relative/friend is unable to consent to take part, or loses the ability to consent?

All participants in research are invited to complete a consent form before the research commences. Sometimes people with dementia are unable to make a decision to consent to a research project because they have difficulty in understanding or retaining the information provided about the project. Sometimes people with dementia are able to do this at the beginning of the project, but later may not be able to provide their consent. In either of these circumstances, the research team is required to consult with someone who is involved in the person's care, such as a family member, regarding whether the person should participate, or continue to participate, in the project. If concerns do arise regarding the your relatives'/friends' ability to consent, we would seek your advice regarding whether the person should participate and what you think the person's feelings and wishes would be regarding taking part. If the person has previously made an advance statement or advanced decision that is relevant, we would not do anything to go against this.

What are the possible disadvantages and risks of taking part?

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. During the training and support, you will be given guidance on what to do if the person with dementia becomes distressed in sessions. If the intervention really does not suit you or the person you are caring for, you are free to finish at any point.

What are the possible benefits of taking part?

If you decide to take part, and your relative/friend is involved in iCST, we hope that this may be of some help to them. Previously, people participating in group CST have reported that they have enjoyed the experience greatly. For all participants, the information we get from this study may help us to treat people with memory problems better in the future.

Will my taking part in the study be kept confidential?

We will ask for your permission to send your relative/friend's GP a letter explaining that you have both agreed to take part in the study. All information which is collected about you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?

You and your relative/friend will be free to withdraw from the study at any time, without

giving a reason. Withdrawing from the study will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

Consent form for use of film footage

Some sessions of Individualised Cognitive Stimulation Therapy (iCST) may be video taped. The purpose of video taping is to help train future volunteers and group facilitators. You may at any point request that video taping is stopped, withdraw your consent for the taping and any further use of the taped footage, at this stage the tape will be edited and destroyed.

What if something goes wrong?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

Who is organising and funding the research?

The research is funded by Health Technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

What will happen to the results of the research?

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the X Ethics Committee.

Who can I contact for further information?

For more information about this research, please contact:

Martin Orrell,
Professor of Ageing and Mental Health,
Charles Bell House, UCL
67-73 Riding House Street, London, W1W 7EJ,
Phone: 020-7679-9452
Email: m.orrell@ucl.ac.uk

Or if you have any complaints about this study please contact:

Fiona Horton R&D Administrator
R& D Department, NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB

Phone 0844 600 1200 Ext 4485
Fax 0844 493 0289

Email: Fiona.Horton@nelft.nhs.uk

Thank you for considering taking part in this research study!

PARTICIPANT INFORMATION SHEET

Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

Invitation to participate in a research study

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?

In recent years, Cognitive Stimulation Therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. This project will show whether individualised (one-to-one) CST is effective in improving things like memory and quality of life for people with memory problems.

What happens in individualised cognitive stimulation therapy (iCST)?

iCST sessions will last for 30 minutes and will be led by your relative/friend. They will take place three times a week for 25 weeks. The activities will include, for example, discussion of food and current affairs. The idea is to keep the mind active through enjoyable activities.

Why have I been chosen?

You have been invited to take part because you have at some point had a memory assessment. We need a large number of people with memory problems to help us evaluate iCST – 260 in total.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

This study is a randomised trial. We need to see whether iCST is better than no treatment, so we need to compare any changes experienced by people receiving iCST to those receiving nothing. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of receiving iCST. The decision is made by an independent computer, which will not have any identifying information about you or your relative/friend.

If you decide to take part, your participation in the study will last for a time period of about six months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Meet with a researcher for between one / one-and-a-half hours for an interview and to complete some questionnaires covering your quality of life, cognition (e.g. memory) and mood. The time stated to complete the interviews and questionnaires is an estimate; you and your friend/relative may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.
2. Repeat these questionnaires with the researcher after 13 weeks and then after another 13 weeks. This is to see whether any of these factors change as a result of the iCST intervention.

Usually, the researcher will come to your home or the home of your relative/friend, but will be happy to meet you elsewhere if you would prefer. The researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

Expenses

Any travel expenses incurred by yourself or your care-giver will be reimbursed.

What do I have to do?

Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you keep your appointments with us during the time that you are taking part.

What are the possible disadvantages and risks of taking part?

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. Your caregiver will be given guidance on what to do if you become anxious or distressed during sessions. If the intervention really does not suit you, you are free to finish at any point.

What are the possible benefits of taking part?

If you decide to take part and receive iCST, we hope that it might be enjoyable for you. We also anticipate that the stimulating activities might improve some of your skills, including memory and language, and improve your quality of life. Such changes have been demonstrated through group CST. The information that we get from this study may help us to treat people with memory problems better in the future, so you will be making a valuable contribution.

Will my taking part in the study be kept confidential?

We will ask for your permission to send your GP a letter explaining that you have agreed to take part in the study. All information which is collected about you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?

You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care you receive. We will need to use any data collected in the study, up to the point of withdrawal.

What if something goes wrong?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

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What will happen to the results of the research?

The results will be published by the Department of Health, and in relevant health journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the X Ethics Committee.

Who can I contact for further information?

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Martin Orrell,
Professor of Ageing and Mental Health,
Charles Bell House, UCL
67-73 Riding House Street, London, W1W 7EJ,

Phone: 020-7679-9452

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Or if you have any complaints about this study please contact:

Fiona Horton R&D Administrator
R& D Department, NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB

Phone 0844 600 1200 Ext 4485

Fax 0844 493 0289

Email: Fiona.Horton@nelft.nhs.uk

Thank you for considering taking part in this research study!

Caregiver Consent Form (MCA)

Participant Identification Number for this trial _____

Individualised Cognitive Stimulation Therapy (iCST) Groups for People with Dementia

Name of Researcher:.....

Please Initial Boxes

1. I confirm that I have read and understand the information sheet (Version X) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care or legal rights of myself or my relative being affected.
3. I understand that sections of any of my relative's medical notes may be looked at by individuals involved in the trial or from regulatory authorities where it is relevant to taking part in this research.
4. I give permission for my relative's GP to be informed of our participation in the study.
5. I have been consulted regarding the participation of my relative, as required by the Mental Capacity Act, and I believe they would wish to take part / continue to take part in the study.

6. I understand that my relative and I will each participate in interviews with a member of the research team as part of this study.

Name of Caregiver

Date

Signature

Name of relative

**Name of Person taking consent
(if different from the researcher)**

Date

Signature

Researcher

Date

Signature

Participant Consent Form

Participant Identification Number for this trial _____

Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia

Name of Researcher:.....

Please Initial Boxes

1. I confirm that I have read and understand the information sheet (Version X) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that sections of any of my medical notes may be looked at by individuals involved in the trial or from regulatory authorities where it is relevant to my taking part in this research. I give my permission for these individuals to have access to my Records.

4. I give permission for my GP to be informed of my participation in the study.

5. I understand that all information given by me or about me will be treated as confidential by the research team.

6. I understand that my carer and I will each participate in interviews with a member of the research team as part of this study.

7. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person taking consent
(if different from the researcher)

Date

Signature

Researcher

Date

Signature

Name of Carer

Date

Signature

iCST: Individual Cognitive Stimulation Therapy for People with Dementia**Participant Eligibility Sheet**

This sheet should be completed by project researchers conducting baseline interviews with participants and carers.

General Instructions to Interviewer

Before commencing the interview, please insert the **Participant Identity Number** on the questionnaire booklet (using the boxes below).

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

At the end of the interview please complete the boxes below.

Thank you for your cooperation.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which assessment is this? *Please tick one box only.*

Baseline Assessment

☐

1st Follow-up

☐

(13 weeks after baseline)

2nd Follow-up

☐

(26 weeks after baseline)

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Eligibility Criteria

Please check these criteria for the participant and tick the appropriate box for each row:

- | | | | | |
|-----|---|----------------------------|------------------------------|-----------------------------|
| 1. | DSM-IV criteria met: | See Sheet 2 & 3 | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. | MMSE Score 10 or above | See QB1 | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. | CAPE – BRS Score 0 or 1 for both items: | See Sheet 3 | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4a. | Participant living in community at baseline: | | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4b. | Care-giver who maintains regular contact, would be willing and able to participate regularly in the intervention and can act as an informant: | | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Exclusion Criteria

Please check this exclusion criteria for the participant and tick the appropriate box:

- | | | | |
|----|--|------------------------------|-----------------------------|
| 1. | Does the participant have a major physical illness or sensory impairment | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
|----|--|------------------------------|-----------------------------|

Participants should only be entered into the iCST trial if the 'Yes' box for each row under Eligibility Criteria has been ticked and the 'No' box has been ticked under Exclusion Criteria.

DSM IV Criteria for dementia

- A. The development of multiple cognitive deficits manifested by both
1. memory impairment (impaired ability to learn new information or to recall previously learned information).
 2. one (or more) of the following cognitive disturbances:
 - a) aphasia (language disturbance)
 - b) apraxia (impaired ability to carry out motor activities despite intact motor function)
 - c) agnosia (failure to recognize or identify objects despite intact sensory function)
 - d) disturbance in executive functioning (i.e., planning, organizing, sequencing, abstracting)
- B. The cognitive deficits in Criteria A1 and A2 each cause significant impairment in social or occupational functioning and represent a significant decline from a previous level of functioning.

AND C. Alzheimer's Dementia 290.1. The course is characterised by gradual onset and continuing cognitive decline (the cognitive deficits are not due to vascular dementia or general medical conditions)

OR C. Vascular Dementia (formerly Multi-Infarct Dementia) 290.4. Focal neurological signs and symptoms (e.g., exaggeration of deep tendon reflexes, extensor plantar response, pseudobulbar palsy, gait abnormalities, weakness of an extremity) or laboratory evidence indicative of cerebrovascular

disease (e.g. multiple infarctions involving cortex and underlying white matter) that are judged to be etiologically related to the disturbance (not due to general medical conditions)

OR C. Dementia due to other general medical conditions. There is evidence from the history, physical examination, or laboratory findings that the disturbance is the direct physiological consequence of one of the general medical conditions listed below. (plus all of D above) *Code* Based on etiological general medical condition: 294.9 Dementia due to HIV Disease; 294.1 Dementia due to Head Trauma; 294.1 Dementia due to Parkinson's Disease; 294.1 Dementia due to Huntington's Disease; 290.10 Dementia due to Pick's Disease; 290.10 Dementia due to Creutzfeldt-Jakob Disease; 294.1 Dementia due to other medical condition [indicate the general medical condition not listed above] (e.g., normal-pressure hydrocephalus, hypothyroidism, brain tumour, vitamin B12 deficiency, intracranial radiation).

OR C. Dementia not otherwise specified 294.8

PLUS D and E

D The deficits do not occur exclusively during the course of a delirium.

E The disturbance is not better accounted for by another Axis I disorder (e.g., Major Depressive Disorder, Schizophrenia).

Clifton Assessment Procedures for the Elderly (CAPE) Behaviour Rating Scale (BRS)

Please consider the following statements for the participant, indicating the appropriate response for each.

1. He / she understands what you communicate to him / her (you may use speaking, writing, or gesturing):

*Please indicate which of the following is correct. Please tick **one** box only.*

- understands almost everything you communicate **0** ☐

- understands some of what you communicate **1** ☐

- understands almost nothing of what you communicate **2** ☐

2. He / she communicates in any manner (by speaking, writing, or gesturing):

*Please indicate which of the following is correct. Please tick **one** box only.*

- well enough to make him / herself easily understood at all times **0** ☐

- can be understood sometimes or with some difficulty **1** ☐

- can rarely or never be understood for whatever reason **2** ☐

Diagnosis

The type of dementia is not an eligibility criterion, but would be helpful for analysis purposes (if known).

Please indicate which diagnosis of dementia has been given (if known)?

*Please tick **one** box only.*

Alzheimer's Type ☐

Vascular ☐

Lewy Body ☐

Mixed ☐

Not known ☐

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

Participant Questionnaire

This booklet of questionnaires should be completed by a project researcher in an interview with the participant.

General Instructions to Interviewer

Before commencing with the interview, please insert the **Participant Identity Number** on the questionnaire booklet (using the boxes below).

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

At the end of the interview please complete the boxes below.

Thank you for your cooperation.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which assessment is this? *Please tick one box only.*

Baseline Assessment

☐

1st Follow-up

☐

(13 weeks after baseline)

2nd Follow-up

☐

(26 weeks after baseline)

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Mini Mental State Examination (MMSE)

Questionnaire 1

Instructions: The following questionnaire is divided into two sections. The first section requires vocal responses, (i.e. orientation, memory, and attention) whereas the second part tests ability to name, follow verbal/written commands, write a sentence and copy a complex polygon. Ask the patient each of the following questions.

1. ORIENTATION

Ask for the date. Then ask specifically for parts omitted, e.g. "Can you also tell me what season it is?". Ask in turn "Can you tell me the name of this place?" (town, county, etc.). One point for each correct answer.

	Correct	Incorrect
1. What year are we in?	<input type="checkbox"/>	<input type="checkbox"/>
2. What season is it?	<input type="checkbox"/>	<input type="checkbox"/>
3. What is today's date?	<input type="checkbox"/>	<input type="checkbox"/>
4. What day of the week is it today?	<input type="checkbox"/>	<input type="checkbox"/>
5. What month are we in?	<input type="checkbox"/>	<input type="checkbox"/>
6. What country are we in?	<input type="checkbox"/>	<input type="checkbox"/>
7. What county are we in?	<input type="checkbox"/>	<input type="checkbox"/>
8. What town are we in?	<input type="checkbox"/>	<input type="checkbox"/>
9. Can you tell me the name of this place?	<input type="checkbox"/>	<input type="checkbox"/>
10. What floor of the building are we on?	<input type="checkbox"/>	<input type="checkbox"/>

Score 0-10



2. REGISTRATION

Ask the patient if you may test his memory. Then say the names of 3 unrelated objects, clearly and slowly, about one second for each, “ **Apple, Table, Penny** ”. After you have said all 3, ask the patient to repeat them. This first repetition determines his score (0-3) but keep saying them until he can repeat all 3, up to 6 trials. If he does not eventually learn all 3, recall cannot be meaningfully tested.

Score 0-3

3. ATTENTION AND CALCULATION

Ask the patient to begin with 100 and count backwards by 7. Stop after 5 subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.

If the patient cannot or will not perform this task, ask him to spell the word “world” backwards. The score is the number of letters in correct order. (E.g. dlrow = 5, dlorw = 3).

Score 0-5

4. RECALL

Ask the patient if he can recall the 3 words you previously asked him to remember. Score 0-3.

Score 0-3

LANGUAGE

5. NAMING

Show the patient a wrist watch and ask him what it is. Repeat for pencil. Score 0-2.

Score 0-2

6. REPETITION

Ask the patient to repeat the sentence “**No ifs, ands or buts**” after you. Allow only one trial. Score 0 or 1.

Score 0-1

7. 3-STAGE COMMAND

Give the patient a piece of plain blank paper and ask him to follow the following 3-stage command: “**Take a paper in your right hand, fold it in half, and put in on the floor**” . Score 1 point for each part correctly executed.

Score 0-3

**8. READING**

On a blank piece of paper print the sentence “**Close your eyes**” in letters large enough for the patient to see clearly. Ask him to read it and do what it says. Score 1 point only if he actually closes his eyes.

Score 0-1

9. WRITING

Give the patient a blank piece of paper and ask him to write a sentence for you. Do not dictate a sentence, it is to be written spontaneously. It must contain a subject and verb and be sensible. Correct grammar and punctuation are not necessary.

Score 0-1

10. COPYING

On a clean piece of paper, draw intersecting pentagons, each side about 1 in. (see response sheet provided), and ask the patient to copy it exactly as it is. All 10 angles must be present and 2 must intersect to score 1 point. Tremor and rotation are ignored.

Score 0-1

TOTAL SCORE
(out of 30)**Alzheimer’s Disease Assessment Scale (ADAS-COG)****Questionnaire 2.**

Instructions: Please use the Administration Manual for this measure. The test items should be given in the order indicated. Note that the **Word Recall test is given first** and the **Word Recognition task is given last** with the other cognitive tests given in-between.

1. WORD RECALL

The subject is given 3 trials to learn a list of 10 high-frequency words, printed in block letters on white cards. The patient reads the 10 words exposed for 2 seconds each. The patient then recalls the words aloud. A total of **3 trials** of reading and recall are given. The score equals the mean number of words not recalled on 3 trials (maximum = 10).

At the start of the first trial, give the following instructions: **“I am going to show you some words, printed on these white cards one at a time. Please read each word out loud and try to remember it, because later I will ask you to try to remember all of the words I have shown you. Ready, read the word and try to remember it”.** After the presentation, ask the subject to try to recall as many of the words as possible by saying: **“Good, now tell me all the words you remember that were on the list”.** Two more learning and recall trials follow. For trials 2 and 3, say to the subject: **“Now I’m going to show you that same list again. Read each word out loud and try to remember it”.**

Trial 1			Trial 2			Trial 3		
Recalled		Not Recalled	Recalled		Not Recalled	Recalled		Not Recalled
Home	<input type="checkbox"/>	<input type="checkbox"/>	Skin	<input type="checkbox"/>	<input type="checkbox"/>	Railroad	<input type="checkbox"/>	<input type="checkbox"/>
Coin	<input type="checkbox"/>	<input type="checkbox"/>	Child	<input type="checkbox"/>	<input type="checkbox"/>	Ocean	<input type="checkbox"/>	<input type="checkbox"/>
Railroad	<input type="checkbox"/>	<input type="checkbox"/>	Wheat	<input type="checkbox"/>	<input type="checkbox"/>	Flag	<input type="checkbox"/>	<input type="checkbox"/>
Child	<input type="checkbox"/>	<input type="checkbox"/>	Library	<input type="checkbox"/>	<input type="checkbox"/>	Army	<input type="checkbox"/>	<input type="checkbox"/>
Army	<input type="checkbox"/>	<input type="checkbox"/>	Home	<input type="checkbox"/>	<input type="checkbox"/>	Wheat	<input type="checkbox"/>	<input type="checkbox"/>
Flag	<input type="checkbox"/>	<input type="checkbox"/>	Ocean	<input type="checkbox"/>	<input type="checkbox"/>	Child	<input type="checkbox"/>	<input type="checkbox"/>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	Railroad	<input type="checkbox"/>	<input type="checkbox"/>	Coin	<input type="checkbox"/>	<input type="checkbox"/>
Library	<input type="checkbox"/>	<input type="checkbox"/>	Flag	<input type="checkbox"/>	<input type="checkbox"/>	Skin	<input type="checkbox"/>	<input type="checkbox"/>
Wheat	<input type="checkbox"/>	<input type="checkbox"/>	Coin	<input type="checkbox"/>	<input type="checkbox"/>	Home	<input type="checkbox"/>	<input type="checkbox"/>
Ocean	<input type="checkbox"/>	<input type="checkbox"/>	Army	<input type="checkbox"/>	<input type="checkbox"/>	Library	<input type="checkbox"/>	<input type="checkbox"/>

TOTAL NOT
RECALLEDTOTAL NOT
RECALLEDTOTAL NOT
RECALLED

Score = mean number of words not recalled on three trials
(maximum score = 10)

SCORE

2. NAMING OBJECTS AND FINGERS

The subject is asked to name 12 randomly presented real objects. Give the subject the following instructions: **“Now I am going to show you some objects. I want you to tell me what their names are. What is this called? or What is the name of this thing?”** . If the subject does not respond, the examiner should give the clue for that item provided below. If the subject still does not respond or makes an error, go on to the next object.

ITEM	CLUES	Correct	Incorrect (or not named)
	Flower – (grows in a garden)	<input type="checkbox"/>	<input type="checkbox"/>
	Bed – (used for sleeping in)	<input type="checkbox"/>	<input type="checkbox"/>
	Whistle – (makes a sound when you blow on it)	<input type="checkbox"/>	<input type="checkbox"/>
	Pencil – (used for writing)	<input type="checkbox"/>	<input type="checkbox"/>
	Rattle – (a baby’s toy)	<input type="checkbox"/>	<input type="checkbox"/>
	Mask – (hides your face)	<input type="checkbox"/>	<input type="checkbox"/>
	Scissors – (cuts paper)	<input type="checkbox"/>	<input type="checkbox"/>
	Comb – (used on hair)	<input type="checkbox"/>	<input type="checkbox"/>
	Wallet – (holds your money)	<input type="checkbox"/>	<input type="checkbox"/>
	Harmonica – (a musical instrument)	<input type="checkbox"/>	<input type="checkbox"/>
	Stethoscope – (doctor uses it to listen to your heart)	<input type="checkbox"/>	<input type="checkbox"/>
	Tweezers – (used to pick up things)	<input type="checkbox"/>	<input type="checkbox"/>

**Total Incorrect
(maximum 12)**

The subject is also asked to name the fingers of his/her dominant hand (e.g. thumb, index [pointer/forefinger], middle, ring finger, and little finger/pinky). Give the subject the following instructions: **“Now I am going to point to a part of your hand and I want you to tell me what it’s called. What is this? or What is another name for this finger?”**.

Item	Correct	Incorrect (or not named)
Thumb	<input type="checkbox"/>	<input type="checkbox"/>
Index/forefinger/pointer	<input type="checkbox"/>	<input type="checkbox"/>
Middle	<input type="checkbox"/>	<input type="checkbox"/>
Ring	<input type="checkbox"/>	<input type="checkbox"/>
Little finger/Pinky	<input type="checkbox"/>	<input type="checkbox"/>

Total Incorrect
(maximum 5)

Score

- 0 0-2 items (objects and fingers) named incorrectly
- 1 3-5 items (objects and fingers) named incorrectly
- 2 6-8 items (objects and fingers) named incorrectly
- 3 9-11 items (objects and fingers) named incorrectly
- 4 12-14 items (objects and fingers) named incorrectly
- 5 15-17 items (objects and fingers) named incorrectly

Score
(maximum 5)

3. COMMANDS :

The subject is asked to carry out 5 separate commands with 1 to 5 steps per command. Each command should be read once. If the subject does not respond or makes an error, give the ENTIRE command one more time. Give the following instructions : **“Now I am going to ask you do a few things. First, ...“Make a *FIST*”, “Point to the *CEILING* and then to the *FLOOR*”. Line up a Pencil, Watch, and Card on the table. Say: “Put the *PENCIL ON TOP OF THE CARD* and then *PUT IT BACK*”. “Put the *WATCH* on the *OTHER SIDE OF THE PENCIL* and then *TURN OVER THE CARD*”. Remove items and say: “*TAP EACH SHOULDER TWICE* with *TWO FINGERS* keeping your *EYES SHUT*”. All components must be correct for the response to be scored as correct.**

	Correct	Incorrect (or not performed)
Make a <u>fist</u>	<input type="checkbox"/>	<input type="checkbox"/>
Point to the <u>ceiling</u> and then to the <u>floor</u>	<input type="checkbox"/>	<input type="checkbox"/>
Line up a pencil, watch, and card, on the table		
Put the <u>pencil on top of the card</u> and then <u>put it back</u>	<input type="checkbox"/>	<input type="checkbox"/>
Put the <u>watch</u> on the <u>other side of the pencil</u> and then <u>turn over the card</u>	<input type="checkbox"/>	<input type="checkbox"/>
Tap <u>each shoulder twice</u> , with <u>two fingers</u> , keeping your <u>eyes shut</u>	<input type="checkbox"/>	<input type="checkbox"/>

Score

- 0 All commands correct
- 1 1 command incorrect, 4 commands correct
- 2 2 commands incorrect, 3 commands correct
- 3 3 commands incorrect, 2 commands correct
- 4 4 commands incorrect, 1 command correct
- 5 All 5 commands incorrect

SCORE
(maximum 5)

4. CONSTRUCTIONAL PRAXIS

Give the subject the following instructions: **“On this piece of paper is a shape. Try to draw another one that looks just like this, somewhere on the page”** and (if required) **“Take your time and try to draw it just like this one”**”. The subject should be allowed two attempts for each shape.

	Correct	Incorrect
Circle	<input type="checkbox"/>	<input type="checkbox"/>
Two Overlapping Rectangles	<input type="checkbox"/>	<input type="checkbox"/>
Diamond (Rhombus)	<input type="checkbox"/>	<input type="checkbox"/>
Cube	<input type="checkbox"/>	<input type="checkbox"/>

Score

- 0 All 4 drawings correct
 1 1 form drawn incorrectly
 2 2 forms drawn incorrectly
 3 3 forms drawn incorrectly
 4 4 forms drawn incorrectly
 5 No figures drawn, scribbles; parts of forms; words instead of forms

SCORE
(maximum 5)

5. IDEATIONAL PRAXIS

Give the subject the following instructions: **"I want you to pretend you have written yourself a letter. Take this piece of paper, fold it so that it will fit into the envelope, and then put it into the envelope. Then, seal the envelope, address the envelope to yourself, and show me where the stamp goes".** There are 5 components to this task and each one is underlined in the instructions.

After the first complete instruction only one additional reminder should be given for each component, if the subject forgets or is having difficulty.

	Correct	Incorrect (or not done)
Fold the letter	<input type="checkbox"/>	<input type="checkbox"/>
Put the letter in envelope	<input type="checkbox"/>	<input type="checkbox"/>
Seal the envelope	<input type="checkbox"/>	<input type="checkbox"/>
Address the envelope	<input type="checkbox"/>	<input type="checkbox"/>
Indicate where the stamp goes (put stamp on envelope)	<input type="checkbox"/>	<input type="checkbox"/>

Score

- 0 All components performed correctly
- 1 Failure to perform 1 component
- 2 Failure to perform 2 components
- 3 Failure to perform 3 components
- 4 Failure to perform 4 components
- 5 Failure to perform 5 components

SCORE
(maximum 5)

6. ORIENTATION

The components of orientation are **person, day of the week, date, month, year, season, time of the day, place** . Make sure no watches, clocks, calendars, etc. are visible to the subject. One restatement of question is allowed (e.g. if subject confuses day and date).

Item	Correct	Incorrect (or not given)
Full name	<input type="checkbox"/>	<input type="checkbox"/>
Day of the Week	<input type="checkbox"/>	<input type="checkbox"/>
Date	<input type="checkbox"/>	<input type="checkbox"/>
Month	<input type="checkbox"/>	<input type="checkbox"/>
Year	<input type="checkbox"/>	<input type="checkbox"/>
Season	<input type="checkbox"/>	<input type="checkbox"/>
Time of Day	<input type="checkbox"/>	<input type="checkbox"/>
Place	<input type="checkbox"/>	<input type="checkbox"/>

Score = 1 point
is given for each incorrect response

SCORE
(maximum 8)

Acceptable answers include: Date: +/- one day, Time: +/- one hour, Place: Partial name acceptable (e.g., name of hospital, clinic, or professional building), Season: Within one week prior to onset or within two weeks of termination. Month, Year, Day of the Week, and the subject's first and last name must be exact.

7. WORD RECOGNITION

Give the subject the following instructions: **“I am going to show you some words printed on these white cards. I want you to read each word out loud and try to remember it”.** Continue with the following instructions: **“Now I’m going to show you another set of words. Some of the words were on the list I just showed you, and others are new. For each word, I want you to tell me whether it is one of the words I just showed you”.**

Then say: **“Is this one of the words I showed you before, yes or no?”** or **“Did I show you this word before?”** or **“How about this one?”**

If the subject does not remember the task (e.g., reads the word rather than responding “Yes” or “No”), then repeat or rephrase the entire question and make a note that the subject had to be reminded of the task instructions. The score equals the mean number of incorrect responses for the **3 trials** (maximum = 12).

Trial 1: score	<div></div>	Reminders	<div></div>
Trial 2: score	<div></div>	Reminders	<div></div>
Trial 3: score	<div></div>	Reminders	<div></div>
Score (mean number of incorrect responses for three trials) (maximum = 12)	<div></div>	Total Reminders (for scoring item 8)	<div></div>

WORD RECOGNITION

Bold words are the words shown before. Italicized words are the words that the subject has not seen. Tick the subject's responses; circles = incorrect responses.

TRIAL 1				TRIAL 2				TRIAL 3			
	Yes/ Shown before	No/ New	Rem		Yes/ Shown before	No/ New	Rem		Yes/ Shown before	No/ New	Rem
<i>Corn</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	River	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Plant</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Effort</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Officer</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	River	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
<i>Party</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Thought</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Amount</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
River	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Event	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Event	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
<i>Folly</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Queen	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Queen	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
<i>Locker</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Position	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Industry</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Event	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Camp</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Position	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
Queen	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Fate</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Occasion</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Position	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Golf</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dove	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
<i>Quality</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dove	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Cradle</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Sunset</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Belief	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Banality</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dove	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Permission</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Singer</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Belief	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Umbrella	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Belief	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
Umbrella	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Hint	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Umbrella	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
<i>Allegory</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Missile	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Hypothesis</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Hound</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Blister</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Hint	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
<i>Idiom</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Concept</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Missile	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
Hint	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Proxy	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Proxy	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
Missile	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Pianist</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Noose</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Gem</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lobster	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Distinction</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Proxy	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Gender</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lobster	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
Lobster	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	Criterion	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Tank</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Criterion	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Bullet</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	Criterion	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>
<i>Deceit</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Intellect</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Decree</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total circles ticked (incorrect responses)				Total circles ticked (incorrect responses)				Total circles ticked (incorrect responses)			

Rem = reminded of instructions



8. REMEMBERING TEST INSTRUCTIONS

On each recognition trial, the subject is asked prior to presentation of the first two words : **“Did I show you this word before, or is this a new word?”**. For the third word, the subject is asked: **“How about this one?”**. The procedure used for the third word is repeated for words 4-24. Each instance of memory failure for the test instructions is noted.

Score: 0 = Subject never needs extra reminders of instructions

1 = Very mild – forgets once

2 = Mild – must be reminded 2 times

3 = Moderate – must be reminded 3 or 4 times

4 = Moderately severe – must be reminded 5 or 6 times

5 = Severe – must be reminded 7 or more times

SCORE
maximum 5)

9. SPOKEN LANGUAGE ABILITY

This item is a global rating of the quality of speech , *i.e.*, clarity, difficulty in making oneself understood. In rating this item the tester should consider all of the speech produced by the subject during the test session. Quantity of speech and word finding difficulty are not rated on this item.

Score: 0 = No instances when it is difficult to understand the subject

1 = Very mild – one instance of lack of understandability

2 = Mild – subject has difficulty less than 25% of the time

3 = Moderate – subject has difficulty 25-50% of the time

4 = Moderately severe – subject has difficulty more than 50% of the time

5 = Severe – one or two word utterance; fluent, but empty speech; mute

SCORE
(maximum 5)

10. WORD-FINDING DIFFICULTY IN SPONTAENEOUS SPEECH

Along with Spoken Language Ability, this item rates impairment in expressive speech, but it rates **only word finding difficulty**. To rate this item, the tester must determine whether the subject has difficulty in finding the desired word in spontaneous speech. The problem may be overcome by circumlocution, *i.e.* giving explanatory phrases or nearly satisfactory synonyms. Do not include finger and object naming in this rating.

QB1

Sheet
No.

14

- Score:
- 0 = No evidence of word finding difficulty in spontaneous speech
 - 1 = Very mild – 1 or 2 instances, not clinically significant
 - 2 = Mild – noticeable circumlocution or synonym substitution
 - 3 = Moderate – loss of words without compensation on occasion
 - 4 = Moderately severe – frequent loss of words without comprehension
 - 5 = Severe – near total loss of content of words; speech sounds empty;
1 -2 word utterances

SCORE
(maximum 5)

11. COMPREHENSION

This item rates the subject's ability to understand speech. To rate this item, the tester considers how well the subject was able to understand the tester's speech during the opening discussion and during the test session. Do not include responses to commands.

- Score:
- 0 = No evidence of poor comprehension
 - 1 = Very mild – 1 or 2 instances of misunderstanding
 - 2 = Mild – 3-5 instances of misunderstanding
 - 3 = Moderate – requires several repetitions and rephrasing
 - 4 = Moderately severe – subject only occasionally responds correctly, *i.e.*, yes/no questions
 - 5 = Severe – subject rarely responds to questions appropriately, not due to poverty of speech

SCORE
(maximum 5)

**12. CONCENTRATION/DISTRACTABILITY**

This item rates the frequency with which the patient is distracted by irrelevant stimuli and/or must be reoriented to the ongoing task because of loss of train of thought or the frequency with which the patient appears to be caught up in his or her own thoughts.

Score: 0 = No evidence of poor concentration or distractibility

1 = Very mild; one instance of poor concentration

2 = Mild; 2-3 instances of poor concentration/distractibility; signs of restlessness and inattentiveness

3 = Moderate; 4-5 instances during interview

4 = Moderately severe; poor concentration/distractibility throughout much of interview

5 = Severe; extreme difficulty in concentration and extremely distractible, unable to complete tasks

SCORE
(maximum 5)



ADAS-COG SCORE SUMMARY SHEET

1. WORD RECALL (maximum 10)	<input type="text"/>	<input type="text"/>
2. NAMING OBJECTS AND FINGERS (maximum 5)	<input type="text"/>	<input type="text"/>
3. COMMANDS (maximum 5)	<input type="text"/>	<input type="text"/>
4. CONSTRUCTIONAL PRAXIS (maximum 5)	<input type="text"/>	<input type="text"/>
5. IDEATIONAL PRAXIS (maximum 5)	<input type="text"/>	<input type="text"/>
6. ORIENTATION (maximum 8)	<input type="text"/>	<input type="text"/>
7. WORD RECOGNITION TASK (maximum 12)	<input type="text"/>	<input type="text"/>
8. REMEMBERING TEST INSTRUCTIONS (maximum 5)	<input type="text"/>	<input type="text"/>
9. SPOKEN LANGUAGE ABILITY (maximum 5)	<input type="text"/>	<input type="text"/>
10. WORD FINDING DIFFICULTY IN SPONTANEOUS SPEECH (maximum 5)	<input type="text"/>	<input type="text"/>
11. COMPREHENSION (maximum 5)	<input type="text"/>	<input type="text"/>
12. CONCENTRATION/DISTRACTABILITY (maximum 5)	<input type="text"/>	<input type="text"/>
TOTAL SCORE (maximum 75)		<input type="text"/>

Questionnaire 3. Instructions: Please administer according to **QOL-AD** standard instructions, using the response sheet. Please indicate the response given by ticking the appropriate box for **each** row.

	Poor	Fair	Good	Excellent	Unable to Choose / Missing
1. Physical health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Mood	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Living situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Memory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Marriage (or close kin)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Self as a whole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Ability to do chores around the house	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Ability to do things for fun	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Money (financial situation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Life as a whole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

DEMQOL

Questionnaire 4. Instructions: Please administer according to **DEMQOL** standard instructions, using the response sheet.

For all of the questions I'm going to ask you, I want you to think about the last week.

First I'm going to ask about your feelings. In the last week, have you felt

	A lot	Quite a bit	A little	Not at all
1. Cheerful?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. That you are enjoying life?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Confident?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Full of energy?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Lonely?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Lively?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. That there are things that you wanted to do but couldn't?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Next, I'm going to ask you about your memory. In the last week, how worried have you been about.....

	A lot	Quite a bit	A little	Not at all
14. Forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Forgetting who people are?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Your thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Poor concentration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about

	A lot	Quite a bit	A little	Not at all
20. Not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. How you get on with people close to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Getting the affection that you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. People not listening to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Making yourself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Getting help when you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Getting to the toilet in time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. How you feel in yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Your health overall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

We've already talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate ...

	Very good	Good	Fair	Poor
29. Your quality of life overall?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

** items that need to be reversed before scoring

Other total ☐☐☐☐

Questionnaire 5. Instructions: The carer referred to here is the person who is completing the questionnaire booklets. Response sheets are provided for this questionnaire. Please indicate the response given by ticking the appropriate box for **each** row. Ask the participant to think of their relationship with the person who is caring for them, when answering the questions.

1. My carer *[or use name of carer]* and I often spend time together in an enjoyable way.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. My carer *[or use name of carer]* and I often disagree.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. There is a big distance in the relationship between my carer *[or use name of carer]* and myself.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. My carer *[or use name of carer]* and I accept each other as we are.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. If there are problems my carer *[or use name of carer]* and I can usually resolve these easily.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. I get on well with my carer *[or use name of carer]*.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. My carer *[or use name of carer]* and I are tender towards each other.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. My carer *[or use name of carer]* often annoys me.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. I feel very good if I am with my carer *[or use name of carer]*.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. My carer *[or use name of carer]* and I often try to impose our opinions on each other.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. I blame my carer *[or use name of carer]* for the cause of my problems.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. My carer *[or use name of carer]* and I appreciate each other as people.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. My carer *[or use name of carer]* does not appreciate enough what I do for him/her.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. I am always glad to see him/her if I have not seen him/her for some time.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Geriatric Depression Scale: Short Form

Questionnaire 6. Instructions: Ask the participant to choose the best answer for how they have felt over the past week. Response sheets are provided for this questionnaire.

		Yes	No
1.	Are you basically satisfied with your life?	<input type="checkbox"/>	<input type="checkbox"/>
2.	Have you dropped many of your activities and interests?	<input type="checkbox"/>	<input type="checkbox"/>
3.	Do you feel that your life is empty?	<input type="checkbox"/>	<input type="checkbox"/>
4.	Do you often get bored?	<input type="checkbox"/>	<input type="checkbox"/>
5.	Are you in good spirits most of the time?	<input type="checkbox"/>	<input type="checkbox"/>
6.	Are you afraid that something bad is going to happen to you?	<input type="checkbox"/>	<input type="checkbox"/>
7.	Do you feel happy most of the time?	<input type="checkbox"/>	<input type="checkbox"/>
8.	Do you often feel helpless?	<input type="checkbox"/>	<input type="checkbox"/>
9.	Do you prefer to stay at home, rather than going out and doing new things?	<input type="checkbox"/>	<input type="checkbox"/>
10.	Do you feel you have more problems with memory than most?	<input type="checkbox"/>	<input type="checkbox"/>
11.	Do you think it is wonderful to be alive?	<input type="checkbox"/>	<input type="checkbox"/>
12.	Do you feel pretty worthless the way you are now?	<input type="checkbox"/>	<input type="checkbox"/>
13.	Do you feel full of energy?	<input type="checkbox"/>	<input type="checkbox"/>
14.	Do you feel that your situation is hopeless?	<input type="checkbox"/>	<input type="checkbox"/>
15.	Do you think that most people are better off than you are?	<input type="checkbox"/>	<input type="checkbox"/>

[illegible]

9

1

1

$$\boxed{}\boxed{} / \boxed{}\boxed{} / \boxed{}\boxed{}\boxed{}\boxed{}$$

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Questionnaire 1

This survey asks for your views about your health, how you feel and how well you are able to do your usual activities. Thank you for completing this survey. For each of the following questions, please place a tick in the box that best describes your answer. Please tick **one** box for **each** item.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a) <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	Yes, limited a lot <input type="checkbox"/>	Yes, limited a little <input type="checkbox"/>	No, not limited at all <input type="checkbox"/>
---	--	---	--

a) Climbing <u>several</u> flights of stairs	Yes, limited a lot <input type="checkbox"/>	Yes, limited a little <input type="checkbox"/>	No, not limited at all <input type="checkbox"/>
--	--	---	--

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a) <u>Accomplished less</u> than you would like	All of the time <input type="checkbox"/>	Most of the time <input type="checkbox"/>	Some of the time <input type="checkbox"/>	A little of the time <input type="checkbox"/>	None of the time <input type="checkbox"/>
---	---	--	--	--	--

b) Were limited in the <u>kind</u> of work or other activities	All of the time <input type="checkbox"/>	Most of the time <input type="checkbox"/>	Some of the time <input type="checkbox"/>	A little of the time <input type="checkbox"/>	None of the time <input type="checkbox"/>
--	---	--	--	--	--

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

- | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) <u>Accomplished less</u>
than you would like | All of
the time | Most of
the time | Some of
the time | A little of
the time | None of
the time |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did work or other
activities <u>less</u>
<u>carefully than usual</u> | All of
the time | Most of
the time | Some of
the time | A little of
the time | None of
the time |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

- | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a) Have you felt calm
and peaceful? | All of
the time | Most of
the time | Some of
the time | A little of
the time | None of
the time |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b) Did you have a
lot of energy? | All of
the time | Most of
the time | Some of
the time | A little of
the time | None of
the time |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c) Have you felt
downhearted
and low? | All of
the time | Most of
the time | Some of
the time | A little of
the time | None of
the time |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends and relatives, etc.)?

All of
the time☐Most of
the time☐Some of
the time☐A little of
the time☐None of
the time☐

Questionnaire 2

The questionnaire below asks about feelings. Please read each item and tick the box for the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies; Your immediate reaction to each item will probably be more accurate than a long thought out response. *Please tick **one box** for each item.*

I feel tense or 'wound up':

- | | |
|---------------------------------|--------------------------|
| Most of the time | <input type="checkbox"/> |
| A lot of the time | <input type="checkbox"/> |
| From time to time, occasionally | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

I still enjoy the things I used to enjoy:

- | | |
|--------------------|--------------------------|
| Definitely as much | <input type="checkbox"/> |
| Not quite so much | <input type="checkbox"/> |
| Only a little | <input type="checkbox"/> |
| Hardly at all | <input type="checkbox"/> |

I get a sort of frightened feeling as if something awful is about to happen:

- | | |
|-----------------------------------|--------------------------|
| Very definitely and quite badly | <input type="checkbox"/> |
| Yes, but not too badly | <input type="checkbox"/> |
| A little, but it doesn't worry me | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

I can laugh and see the funny side of things:

- | | |
|----------------------------|--------------------------|
| As much as I always could | <input type="checkbox"/> |
| Not quite so much now | <input type="checkbox"/> |
| Definitely not so much now | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |



Worrying thoughts go through my mind:

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

I feel cheerful:

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

I can sit at ease and feel relaxed:

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

I feel as if I am slowed down:

- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

I get a sort of frightened feeling like 'butterflies' in the stomach:

- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

I have lost interest in my appearance:

- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

I feel restless as if I have to be on the move:

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

I look forward with enjoyment to things:

- As much as I ever did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

I get sudden feelings of panic:

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

I can enjoy a good book or radio or TV programme:

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Questionnaire 3

By placing a tick in **one** box in **each** group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

Pain/Discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

Anxiety/Depression:

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

For office use only			
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Best imaginable health state

100



Worst imaginable health state

Questionnaire 4

Please think about your relationship with the person you are caring for and answer the following questions by ticking the appropriate box. *Please tick **one box** in **each** row.*

1. My relative and I often spend time together in an enjoyable way.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. My relative and I often disagree.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. There is a big distance in the relationship between my relative and myself.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. My relative and I accept each other as we are.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. If there are problems my relative and I can usually resolve these easily.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. I get on well with my relative.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. My relative and I are tender towards each other.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. My relative often annoys me.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. I feel very good if I am with my relative.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. My relative and I often try to impose our opinions on each other.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. I blame my relative for the cause of my problems.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. My relative and I appreciate each other as people.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. My relative does not appreciate enough what I do for him/her.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. I am always glad to see him/her if I have not seen him/her for some time.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Questionnaire 5

Please read the following statements. To the right of each you will find seven numbers, ranging from "1" (Strongly Disagree) on the left to "7" (Strongly Agree) on the right. Tick the box underneath the number that best indicates your feelings about that statement. *Please tick **one box** in each row.*

1. I usually manage one way or another.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. I feel proud that I have accomplished things in life.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. I usually take things in stride.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. I am friends with myself.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



5. I feel that I can handle many things at a time.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. I am determined.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. I can get through difficult times because I've experienced difficulty before.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. I have self-discipline.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. I keep interested in things.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



10. I can usually find something to laugh about.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. My belief in myself gets me through hard times.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. In an emergency, I'm someone people can generally rely on.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. My life has meaning.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. When I'm in a difficult situation, I can usually find my way out of it.

Strongly Disagree				Neutral			Strongly Agree
1	2	3	4	5	6	7	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**Thank you for completing these questionnaires.
Your help is very appreciated.**

Questionnaire 1

<p>Instructions: When you think about your relative's life, there are different aspects, some of which are listed below. Please rate these items based on your relative's life at the present time (e.g. within the past few weeks). Please indicate your response by ticking the appropriate box for each row.</p>					
		Poor	Fair	Good	Excellent
1.	Physical health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Mood	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Living situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Memory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	Family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Marriage (or close kin)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Self as a whole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Ability to do chores around the house	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Ability to do things for fun	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Money (financial situation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	Life as a whole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Questionnaire 2

Instructions: For each activity described below, statements a-e refer to a different level of every-day ability for your relative. Thinking about the last 2 weeks, tick the box that represents your relative's ability. *Please tick **one** box for **each** activity.*

1. Food *Please tick **one** box.*

- | | | |
|---|--|--------------------------|
| a | Selects and prepares food as required | <input type="checkbox"/> |
| b | Able to prepare food if ingredients set out | <input type="checkbox"/> |
| c | Can prepare food if prompted step by step | <input type="checkbox"/> |
| d | Unable to prepare food even with prompting and supervision | <input type="checkbox"/> |
| e | Not applicable | <input type="checkbox"/> |

2. Eating *Please tick **one** box.*

- | | | |
|---|--|--------------------------|
| a | Eats appropriately using correct cutlery | <input type="checkbox"/> |
| b | Eats appropriately if food made manageable and/or uses spoon | <input type="checkbox"/> |
| c | Uses fingers to eat food | <input type="checkbox"/> |
| d | Needs to be fed | <input type="checkbox"/> |
| e | Not applicable | <input type="checkbox"/> |

3. Drink *Please tick **one** box.*

- | | | |
|---|--|--------------------------|
| a | Selects and prepares drinks as required | <input type="checkbox"/> |
| b | Can prepare drinks if ingredients left available | <input type="checkbox"/> |
| c | Can prepare drinks if prompted step by step | <input type="checkbox"/> |
| d | Unable to make a drink even with prompting and supervision | <input type="checkbox"/> |
| e | Not applicable | <input type="checkbox"/> |

4. Drinking *Please tick **one** box.*

- | | | |
|---|---|--------------------------|
| a | Drinks appropriately | <input type="checkbox"/> |
| b | Drinks appropriately with aids, beaker/straw etc. | <input type="checkbox"/> |
| c | Does not drink appropriately even with aids but attempts to | <input type="checkbox"/> |
| d | Has to have drinks administered (fed) | <input type="checkbox"/> |
| e | Not applicable | <input type="checkbox"/> |

5. Dressing *Please tick **one** box.*

- a Selects appropriate clothing and dresses self ☐
- b Puts clothes on in wrong order and/or back to front and/or dirty clothing ☐
- c Unable to dress self but moves limbs to assist ☐
- d Unable to assist and requires total dressing ☐
- e Not applicable ☐

6. Hygiene *Please tick **one** box.*

- a Washes regularly and independently ☐
- b Can wash self if given soap, flannel, towel, etc. ☐
- c Can wash self if prompted and supervised ☐
- d Unable to wash self and needs full assistance ☐
- e Not applicable ☐

7. Teeth *Please tick **one** box.*

- a Cleans own teeth/dentures regularly and independently ☐
- b Cleans teeth/dentures if given appropriate items ☐
- c Requires some assistance, toothpaste on brush, brush to mouth etc. ☐
- d Full assistance given ☐
- e Not applicable ☐

8. Bath/Shower *Please tick **one** box.*

- a Bathes regularly and independently ☐
- b Needs bath to be drawn/shower turned on but washes independently ☐
- c Needs supervision and prompting to wash ☐
- d Totally dependent, needs full assistance ☐
- e Not applicable ☐

9. Toilet/Commode *Please tick **one** box.*

- a Uses toilet appropriately when required ☐
- b Needs to be taken to the toilet and given assistance ☐
- c Incontinent of urine or faeces ☐
- d Incontinent of urine and faeces ☐
- e Not applicable ☐

10. Transfers *Please tick **one** box.*

- a Can get in/out of a chair unaided ☐
- b Can get into a chair but needs help to get out ☐
- c Needs help getting in and out of a chair ☐
- d Totally dependent on being put into and lifted from chair ☐
- e Not applicable ☐

11. Mobility *Please tick **one** box.*

- a Walks independently ☐
- b Walks with assistance, i.e. furniture, arm for support ☐
- c Uses aids to mobilize, i.e. frame, sticks etc. ☐
- d Unable to walk ☐
- e Not applicable ☐

12. Orientation - Time *Please tick **one** box.*

- a Fully orientated to time/day/date etc. ☐
- b Unaware of time/day etc. but seems unconcerned ☐
- c Repeatedly asks the time/day/date ☐
- d Mixes up night and day ☐
- e Not applicable ☐

13. Orientation - Space *Please tick **one** box.*

- a Fully orientated to surroundings ☐
- b Orientated to familiar surroundings only ☐
- c Gets lost in home, needs reminding where bathroom is, etc. ☐
- d Does not recognise home as own and attempts to leave ☐
- e Not applicable ☐

14. Communication *Please tick **one** box.*

- a Able to hold appropriate conversation ☐
- b Shows understanding and attempts to respond verbally with gestures ☐
- c Can make self understood but difficulty understanding others ☐
- d Does not respond to or communicate with others ☐
- e Not applicable ☐

15. Telephone *Please tick **one** box.*

- a Uses telephone appropriately, including obtaining correct number ☐
- b Uses telephone if number given verbally/visually, or predialled ☐
- c Answers telephone but does not make calls ☐
- d Unable/unwilling to use telephone at all ☐
- e Not applicable ☐

16. Housework/Gardening *Please tick **one** box.*

- a Able to do housework/gardening to previous standard ☐
- b Able to do housework/gardening but not to previous standard ☐
- c Limited participation even with a lot of supervision ☐
- d Unwilling/unable to participate in previous activities ☐
- e Not applicable ☐

17. Shopping *Please tick **one** box.*

- a Shops to previous standard ☐
- b Only able to shop for 1 or 2 items with or without a list ☐
- c Unable to shop alone, but participates when accompanied ☐
- d Unable to participate in shopping even when accompanied ☐
- e Not applicable ☐

18. Finances *Please tick **one** box.*

- a Responsible for own finances at previous level ☐
- b Unable to write cheque but can sign name and recognises money values ☐
- c Can sign name but unable to recognise money values ☐
- d Unable to sign name or recognise money values ☐
- e Not applicable ☐

19. Games/Hobbies *Please tick **one** box.*

- a Participates in pastimes/activities to previous standard ☐
- b Participates but needs instruction/supervision ☐
- c Reluctant to join in, very slow, needs coaxing ☐
- d No longer able or willing to join in ☐
- e Not applicable ☐

20. Transport *Please tick **one** box.*

- a Able to drive, cycle or use public transport independently ☐
- b Unable to drive but uses public transport or bike etc. ☐
- c Unable to use public transport alone ☐
- d Unable/unwilling to use transport even when accompanied ☐
- e Not applicable ☐

QB 3

A large, empty rectangular box with a black border, likely intended for a signature or stamp.

Sheet No.

8

**Thank you for completing these questionnaires
Your help is very appreciated**

General Questionnaire

General Instructions to Interviewer

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

Participant Identity Number:

[illegible]

Centre Name:

Which assessment is this? *Please tick **one** box only.*

Baseline Assessment

7

1st Follow-up

1

(13 weeks after baseline)

2nd Follow-up

1

(26 weeks after baseline)

Completed by (please print name):

Signed:

Interview date:

$$\begin{array}{|c|c|} \hline & \\ \hline \end{array} \bigg/ \begin{array}{|c|c|} \hline & \\ \hline \end{array} \bigg/ \begin{array}{|c|c|c|c|} \hline & & & \\ \hline \end{array}$$

d d m m v v v v

Questionnaire 1

Note to Interviewer: Please interview the carer about each of the following 32 items, using the standard instructions provided. Please indicate each response provided by the carer by ticking the appropriate box for **each** row.

For all of the questions I'm going to ask you, I want you to think about the last week.

First I'm going to ask about ----- (your relative's) feelings. In the last week, would you say that ----- (your relative) has felt.....

	A lot	Quite a bit	A little	Not at all
1. cheerful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. full of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. content?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. lively?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. that he/she has things to look forward to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Next, I'm going to ask you about ----- (your relative's) memory. In the last week, how worried would you say ----- (your relative) has been about ...

	A lot	Quite a bit	A little	Not at all
12. his/her memory in general?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. forgetting things that happened a long time ago?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. forgetting people's names?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. forgetting where he/she is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. his/her thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. making him/herself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Now, I'm going to ask about ----- (your relative's) **everyday life**. In the last week, how worried would you say ----- (your relative) has been about ...

	A lot	Quite a bit	A little	Not at all
21. keeping him/herself clean (e.g. washing and bathing)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. keeping him/herself looking nice?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. getting what he/she wants from the shops?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. using money to pay for things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. looking after his/her finances?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. things taking longer than they used to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. getting in touch with people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. not being able to help other people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. not playing a useful part in things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. his/her physical health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

We've already talked about lots of things: ----- (your relative's) feelings, memory and everyday life. Thinking about all of these things in the last week, how would you say ----- (your relative) would rate ...

	Very good	Good	Fair	Poor
32. his/her quality of life overall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Questionnaire 2. Instructions: Please interview the carer using standard instructions.

A. Delusions - Does the patient have beliefs that you know are not true?

N/A

☐

NO

☐

YES

☐

If yes proceed to subsections

- A1 Does the patient believe that he/she is in danger – that others are planning to hurt him/her? ☐
- A2 Does the patient believe that others are stealing from him/her? ☐
- A3 Does the patient believe that his/her spouse is having an affair? ☐
- A4 Does the patient believe that unwelcome guests are living in his/ her house? ☐
- A5 Does the patient believe that his/her spouse or others are not who they claim to be? ☐
- A6 Does the patient believe that his/her house is not his/her home? ☐
- A7 Does the patient believe that family members plan to abandon him/her? ☐
- A8 Does the patient believe that television or magazine figures are actually present in the home? (does he/she try to talk or interact with them?) ☐
- A9 Does the patient believe any other unusual things that I haven't asked about? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – once or more per day

SEVERITY

- ☐ Mild – delusions present but seem harmless and produce little distress in the patient
- ☐ Moderate – delusions are distressing and disruptive
- ☐ Marked – delusions are very disruptive and are a major source of behavioural disruption (if PRN medications are prescribed, their use signals that the delusions are of marked severity)

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL DELUSIONS
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**

B. Hallucinations – Does the patient have hallucinations such as false visions or voices?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- B1 Does the patient describe hearing voices or act as if he/she hears voices? ☐
- B2 Does the patient talk to people who are not there? ☐
- B3 Does the patient describe seeing things not seen by others or behave as if he/she is seeing things not seen by others (people/animals/lights etc.)? ☐
- B4 Does the patient report smelling odours not smelled by others? ☐
- B5 Does the patient describe feeling things on his/her skin or otherwise appear to be feeling things crawling or touching him/her? ☐
- B6 Does the patient describe tastes that are without any known cause? ☐
- B7 Does the patient describe any other unusual sensory experience? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – once or more per day

SEVERITY

- ☐ Mild – hallucinations present but seem harmless and cause little distress for the patient
- ☐ Moderate – hallucinations are distressing and are disruptive to the patient
- ☐ Marked – hallucinations are very disruptive and are a major source of behavioural disturbance. PRN medications may be required to control them.

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL HALLUCINATIONS
(FREQUENCY X SEVERITY)****TOTAL CAREGIVER
DISTRESS**

C. Agitation/Aggression – Does the patient have periods where he/she refuses to cooperate or won't let people help him/her?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- C1 Does the patient get upset with those trying to care for him/her or resist activities such as bathing or changing clothes? ☐
- C2 Is the patient stubborn, having to have things his/her way? ☐
- C3 Is the patient uncooperative, resistive to help from others? ☐
- C4 Does the patient have any other behaviours that make him/her hard to handle? ☐
- C5 Does the patient shout or curse angrily? ☐
- C6 Does the patient slam doors, kick furniture, throw things? ☐
- C7 Does the patient attempt to hurt or hit others? ☐
- C8 Does the patient have any other aggressive or agitated behaviour? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – once or more per day

SEVERITY

- ☐ Mild – behaviour is disruptive but can be managed with redirection or reassurance
- ☐ Moderate – behaviour is disruptive and difficult to redirect or control
- ☐ Marked – agitation is very disruptive and difficult to redirect or control; there may be a threat of personal harm. Medications are often required.

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL AGITATIONS/AGGRESSION
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**

D. Depression/Dysphoria – Does the patient seem sad or depressed?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- D1 Does the patient have periods of tearfulness or sobbing that seem to indicate sadness? ☐
- D2 Does the patient say or act as if he/she is sad or in low spirits? ☐
- D3 Does the patient put him/herself down or say that he/she feels like a failure? ☐
- D4 Does the patient say that he/she is a bad person or deserves to be punished? ☐
- D5 Does the patient seem very discouraged or say that he/she has no future? ☐
- D6 Does the patient say he/she is a burden to the family or that the family would be better off without him/her? ☐
- D7 Does the patient express a wish for death or talk about killing him/herself? ☐
- D8 Does the patient show any other signs of depression or sadness? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – essentially continuously present

SEVERITY

- ☐ Mild – depression is present but usually responds to redirection or reassurance
- ☐ Moderate – depression is distressing, depressive symptoms are spontaneously voiced by the patient and difficult to alleviate
- ☐ Marked – depression is very distressing and a major source of suffering for the patient

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL DEPRESSION/DYSPHORIA
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**

E. Anxiety – Is the patient very nervous, worried or frightened for no apparent reason?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- E1 Does the patient say that he/she is worried about planned events? ☐
- E2 Does the patient have periods of feeling shaky, unable to relax, or feeling excessively tense? ☐
- E3 Does the patient have periods of (or complain of) shortness of breath, gasping or sighing for no other reason other than nervousness? ☐
- E4 Does the patient complain of butterflies in his/her stomach, or of racing or pounding of the heart in association with nervousness? (Symptoms not explained by ill health) ☐
- E5 Does the patient avoid certain places or situations that make him/her more nervous such as riding in the car, meeting with friends, or being in crowds? ☐
- E6 Does the patient become nervous and upset when separated from you (or his/her caregiver)? (does he/she cling to you to keep from being separated?) ☐
- E7 Does the patient show any other signs of anxiety? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – once or more per day

SEVERITY

- ☐ Mild – anxiety is distressing but usually responds to redirection or reassurance
- ☐ Moderate – anxiety is distressing, anxiety symptoms are spontaneously voiced by the patient and difficult to alleviate
- ☐ Marked – anxiety is very distressing and a major source of suffering for the patient

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL ANXIETY
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**

F. Elation/Euphoria – Does the patient seem to be too cheerful or too happy for no reason?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- F1 Does the patient appear to feel too good or to be too happy, different from his/her usual self? ☐
- F2 Does the patient find humour and laugh at things that others do not find funny? ☐
- F3 Does the patient seem to have a childish sense of humour with a tendency to giggle or laugh inappropriately (such as when unfortunate things happen to others)? ☐
- F4 Does the patient tell jokes or make remarks that have little humour for others but seem funny to him/her? ☐
- F5 Does he/she play childish pranks such as pinking or playing 'keep away' for the fun of it? ☐
- F6 Does the patient 'talk big' or claim to have more abilities or wealth than is true? ☐
- F7 Does the patient show any other signs of feeling too good or being too happy? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – essentially continuously present

SEVERITY

- ☐ Mild – elation is notable to friends and family but is not disruptive
- ☐ Moderate – elation is notably abnormal
- ☐ Marked – elation is very pronounced, patient is euphoric and finds nearly everything to be humorous

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL ELATION/EUPHORIA
(FREQUENCY X SEVERITY)****TOTAL CAREGIVER
DISTRESS**

G. Apathy/Indifference – Has the patient lost interest in the world around him/her?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- G1 Does the patient seem less spontaneous and less active than usual? ☐
- G2 Is the patient less likely to initiate a conversation? ☐
- G3 Is the patient less affectionate or lacking in emotions when compared to his/her usual self? ☐
- G4 Does the patient contribute less to household chores? ☐
- G5 Does the patient seem less interested in the activities and plans of others? ☐
- G6 Has the patient lost interest in friends and family members? ☐
- G7 Is the patient less enthusiastic about his/her usual interests? ☐
- G8 Does the patient show any other signs that she doesn't care about doing new things? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – nearly always present

SEVERITY

- ☐ Mild – apathy is notable but produces little interference with daily routines; only mildly different from patient's usual behaviour; patient responds to suggestion to engage in activities
- ☐ Moderate – apathy is very evident; may be overcome by the caregiver with coaxing and encouragement; responds spontaneously only to powerful events such as visits from close relatives or family members
- ☐ Marked – apathy is very evident and usually fails to respond to any encouragement or external events

CAREGIVER DISTRESS- How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL APATHY/INDIFFERENCE
(FREQUENCY X SEVERITY)****TOTAL CAREGIVER
DISTRESS**

H. Disinhibition – Does the patient seem to act impulsively without thinking?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- H1 Does the patient act impulsively without appearing to consider the consequences? ☐
- H2 Does the patient talk to total strangers as if he/she knew them? ☐
- H3 Does the patient say things to people that are insensitive or hurt their feelings? ☐
- H4 Does the patient say crude things or make sexual remarks that they would not usually have said? ☐
- H5 Does the patient talk openly about very personal or private matters not usually discussed in public? ☐
- H6 Does the patient take liberties or touch or hug others in a way that is out of character for him/her? ☐
- H7 Does the patient show any other signs of loss of control of his/her impulses? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – essentially continuously present

SEVERITY

- ☐ Mild – disinhibition is notable but usually responds to redirection and guidance
- ☐ Moderate – disinhibition is very evident and difficult to overcome by the caregiver
- ☐ Marked – disinhibition usually fails to respond to any intervention by the caregiver, and is a source of embarrassment or social distress

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL DISINHIBITION
(FREQUENCY X SEVERITY)****TOTAL CAREGIVER
DISTRESS**



I. Irritability/Lability – Does the patient get irritated and easily disturbed?

N/A
☐

NO
☐

YES
☐

If yes proceed to subsections

- | | | |
|----|--|--------------------------|
| I1 | Does the patient have a bad temper, flying 'off the handle' easily over little things? | <input type="checkbox"/> |
| I2 | Does the patient rapidly change moods from one to another, being fine one minute and angry the next? | <input type="checkbox"/> |
| I3 | Does the patient have sudden flashes of anger? | <input type="checkbox"/> |
| I4 | Is the patient impatient, having trouble coping with delays or waiting for planned activities? | <input type="checkbox"/> |
| I5 | Is the patient cranky and irritable? | <input type="checkbox"/> |
| I6 | Is the patient argumentative and difficult to get along with? | <input type="checkbox"/> |
| I7 | Does the patient show any other signs of irritability? | <input type="checkbox"/> |

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – essentially continuously present

SEVERITY

- ☐ Mild – irritability or lability is notable but usually responds to redirection and reassurance
- ☐ Moderate – irritability and lability are very evident and difficult to overcome by the caregiver
- ☐ Marked – irritability and lability are very evident, they usually fail to respond to any intervention by the caregiver, and they are a major source of distress

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL IRRITABILITY/LABILITY
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**

J. Aberrant motor behaviour – Does the patient pace, do things over and over such as opening closets or drawers, or repeatedly pick at things or wind string or threads?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- J1 Does the patient pace around the house without any apparent purpose? ☐
- J2 Does the patient rummage around opening and unpacking drawers or closets? ☐
- J3 Does the patient repeatedly put on and take off clothing? ☐
- J4 Does the patient have repetitive activities or 'habits' that he/she performs over and over? ☐
- J5 Does the patient engage in repetitive activities such as handling buttons, picking, wrapping string etc.? ☐
- J6 Does the patient fidget excessively, seem unable to sit still, or bounce his/her feet or tap his/her fingers a lot? ☐
- J7 Does the patient do any other activities over and over? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – essentially continuously present

SEVERITY

- ☐ Mild – abnormal motor activity is notable but produces little interference with daily routines
- ☐ Moderate – abnormal motor activity is very evident; can be overcome by the caregiver
- ☐ Marked – abnormal motor activity is very evident, it usually fails to respond to any intervention by the caregiver and is a major source of distress

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL ABERRANT MOTOR BEHAVIOUR
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**

K. Sleep – Does the patient have difficulty sleeping (do not count as present if the patient simply gets up once or twice per night only to go to the bathroom and falls back asleep immediately)?

N/A

☐

NO

☐

YES

☐**If yes proceed to subsections**

- K1 Does the patient have difficulty falling asleep? ☐
- K2 Does the patient get up during the night (do not count if the patient simply gets up once or twice per night only to go to the bathroom and falls back asleep immediately)? ☐
- K3 Does the patient wander, pace or get involved in inappropriate activities at night? ☐
- K4 Does the patient awaken you during the night? ☐
- K5 Does the patient awaken during the night, dress and plan to go out, thinking that it is morning and time to start the day? ☐
- K6 Does the patient awaken too early in the morning (earlier than was his/her habit)? ☐
- K7 Does the patient sleep excessively during the day? ☐
- K8 Does the patient have any other night-time behaviours that bother you that we haven't talked about? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – once or more per day

SEVERITY

- ☐ Mild – night-time behaviours occur but they are not particularly disruptive
- ☐ Moderate – night-time behaviours occur and disturb the patient and the sleep of the caregiver; more than one type of night-time behaviour may be present
- ☐ Marked – night-time behaviours occur; several types of night-time behaviour may be present; the patient is very distressed during the night and the caregiver's sleep is markedly disturbed

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL SLEEP
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**



L. Appetite and eating disorders – Has he/she had any change in appetite, weight, or eating habits?

N/A

☐

NO

☐

YES

☐

If yes proceed to subsections

- L1 Has he/she had a loss of appetite? ☐
- L2 Has he/she had an increase in appetite? ☐
- L3 Has he/she had a loss of weight? ☐
- L4 Has he/she gained weight? ☐
- L5 Has he/she had a change in eating behaviour such as putting too much food in his/her mouth at once? ☐
- L6 Has he/she had a change in the kind of food he/she likes such as eating too many sweets or other specific types of food? ☐
- L7 Has he/she developed eating behaviours such as eating exactly the same types of food each day or eating the food in exactly the same order? ☐
- L8 Have there been any other changes in appetite or eating that I haven't asked about? ☐

FREQUENCY

- ☐ Occasionally – less than once per week
- ☐ Often – about once per week
- ☐ Frequently – several times per week but less than every day
- ☐ Very frequently – once or more per day

SEVERITY

- ☐ Mild – changes in appetite or eating are present but have not led to changes in weight and are not disturbing
- ☐ Moderate – changes in appetite or eating are present and cause minor fluctuations in weight
- ☐ Marked – obvious changes in appetite or eating are present and cause fluctuations in weight, are embarrassing, or otherwise disturb the patient

CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?

- ☐ Not at all
- ☐ Minimally
- ☐ Mildly
- ☐ Moderately
- ☐ Severely
- ☐ Very severely or extremely

**TOTAL APPETITE AND EATING DISORDERS
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER
DISTRESS**



Neuropsychiatric Inventory (NPI)

SUMMARY SCORE SHEET

	TOTAL SCORE	CAREGIVER DISTRESS
A. Delusions	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
B. Hallucinations	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
C. Agitation/Aggression	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
D. Depression/Dysphoria	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
E. Anxiety	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
F. Elation/Euphoria	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
G. Apathy/Indifference	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
H. Disinhibition	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
I. Irritability/Lability	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
J. Aberrant motor behaviour	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
K. Sleep	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
L. Appetite and eating disorders	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
 TOTAL SCORES	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

Questionnaire 3

Instructions: Please administer this instrument using the instructions provided.

Clinical Dementia Rating Scale**CDR**

Category	Healthy CDR 0	Questionable dementia CDR 0.5	Mild dementia CDR 1	Moderate dementia CDR 2	Severe dementia CDR 3
Memory	No memory loss or slight inconstant forgetfulness	Mild consistent forgetfulness; partial recollection of events; 'benign' forgetfulness	Moderate memory loss, more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
Orientation	Fully orientated		Some difficulty with time relationships; orientated for place and person at examination but may have geographic disorientation	Usually disoriented in time, often to place	Orientation to person only
Judgement + problem solving	Solves every day problems well; judgement good in relation to past performance	Only doubtful impairment in solving problems, similarities, differences	Moderate difficulty in handling complex problems; social judgement usually maintained	Severely impaired in handling problems, similarities, differences; social judgement usually impaired	Unable to make judgements or solve problems
Community affairs	Independent function at usual level in job, shopping, business and financial affairs, volunteer and social groups	Only doubtful or mild impairment, if any, in these activities	Unable to function independently at these activities though may still be engaged in some; may still appear normal to casual inspection	No pretence of independent function outside home	
Home + hobbies	Life at home, hobbies, intellectual interests well maintained	Life at home, hobbies, intellectual interests well maintained or only slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly sustained	No significant function in home outside of own room
Personal care	Fully capable of self care		Needs occasional prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; often incontinent
Score using box overleaf. Score as 0.5, 1, 2, 3 only if impairment is due to cognitive loss.					

Assigning the Clinical Dementia Rating

An algorithm can be used to give the overall CDR score, as follows:

The global CDR score is derived from the scores in each of the six categories. Memory (M) is considered the primary category and all others are secondary. CDR = M if at least three secondary categories are given the same score as memory. Whenever three or more secondary categories are given a score greater or less than the memory score, CDR equals the score of the majority of secondary categories that are on whichever side of M has the greatest number of secondary categories. If there are ties in the secondary categories on one side of M, the CDR score closest to M is chosen.

When M = 0.5, CDR = 1 if at least three of the other categories are scored one or greater.

If M = 0.5, CDR cannot be 0; it can only be 0.5 or 1. If M = 0, CDR = 0 unless there is questionable impairment in two or more secondary categories, in which case CDR = 0.5

Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 0 – No Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 2 – Moderate Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 0.5 – Questionable Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 3 – Severe Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

Mark in only one box for each category. To assign the CDR, see grids on the right. Shaded areas indicate defined range within which the scores of individual subjects must fall to be assigned a given CDR.

Clinical Dementia Rating: 0 ☐

Please tick **one** box only.

0.5 ☐

1 ☐

2 ☐

3 ☐

CDR 1 – Mild Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

Questionnaire 4 – Background Details

This section is completed by interviewing the family carer.

Provide the carer the following information: To help with our study it will be helpful to have some background details about you and your relative. These will allow us to compare groups in the study with the general population. All data is confidential and stored in an anonymised form.

4. 1 What is your relationship to the participant?

Please tick **one** box only

- | | |
|---------------------------------|--------------------------|
| a. Wife/Husband (Spouse) | <input type="checkbox"/> |
| b. Partner | <input type="checkbox"/> |
| c. Son/daughter | <input type="checkbox"/> |
| d. Son/daughter-in-law | <input type="checkbox"/> |
| e. Brother/sister | <input type="checkbox"/> |
| f. Other relative | <input type="checkbox"/> |
| g. Friend | <input type="checkbox"/> |
| h. Neighbour | <input type="checkbox"/> |
| i. Other (please specify) _____ | <input type="checkbox"/> |

4. 2 Please indicate the gender of the participant and carer (tick as appropriate)**Participant**

Male ☐ Female ☐

Carer

Male ☐ Female ☐

4. 3 Age of participant and carer

Participant ☐☐

Carer ☐☐

4.4 Date of birth (dd/mm/yyyy) of participant and carer

Participant ☐☐ / ☐☐ / ☐☐☐☐

Carer ☐☐ / ☐☐ / ☐☐☐☐

4.5 Ethnicity of participant and carer

Participant

☐ **WHITE or**☐ White British☐ White Irish☐ Other White Background☐ **BLACK or BLACK BRITISH or**☐ Caribbean☐ African☐ Other Black Background☐ **MIXED or**☐ White & Black Caribbean☐ White & Black African☐ White and Asian☐ Other Mixed Background☐ **ASIAN or ASIAN BRITISH or**☐ Indian☐ Pakistani☐ Bangladeshi☐ Other Asian Background☐ **CHINESE or OTHER ETHNIC GROUP**☐ Chinese☐ Other ethnic group☐ **NOT STATED / DO NOT WISH TO SPECIFY**

QB 5

Carer

☐ **WHITE or**

☐ White British

☐ White Irish

☐ Other White Background

☐ **BLACK or BLACK BRITISH or**

☐ Caribbean

☐ African

☐ Other Black Background

☐ **MIXED or**

☐ White & Black Caribbean

☐ White & Black African

☐ White and Asian

☐ Other Mixed Background

☐ **ASIAN or ASIAN BRITISH or**

☐ Indian

☐ Pakistani

☐ Bangladeshi

☐ Other Asian Background

☐ **CHINESE or OTHER ETHNIC GROUP**

☐ Chinese

☐ Other ethnic group

☐ **NOT STATED / DO NOT WISH TO SPECIFY**



4.6 Please indicate participant's and carer's marital status
(please tick **one** box)

Participant

- ☐ Single (never married)
- ☐ Married
- ☐ Co-habiting
- ☐ Civil partnership
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

Carer

- ☐ Single (never married)
- ☐ Married
- ☐ Co-habiting
- ☐ Civil partnership
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

4.7 Please indicate participant's and carer's living status.

Participant lives with
(please tick **all** that apply)

- ☐ Spouse/Partner
- ☐ Other family
- ☐ Other
- ☐ No-one

Carer lives with
(please tick **all** that apply)

- ☐ Spouse/Partner
- ☐ Other family
- ☐ Other
- ☐ No-one

4.8 At what age did the participant and carer leave full-time education?

Participant ☐ ☐
Carer ☐ ☐

4.9 Please indicate participant's level of education
(please tick **one** box)

- ☐ School Leaver (14-16 years of age)
- ☐ School Leaver (18 years of age)
- ☐ Further Education (Vocational Qualifications: i.e. GNVQ/NVQ/HND)
- ☐ Higher Education (BSc/BA or equivalent)
- ☐ Postgraduate Education (MSc/MA/PhD or equivalent)

4.10 Please indicate carer's level of education
(please tick **one** box)

- ☐ School Leaver (14-16 years of age)
- ☐ School Leaver (18 years of age)
- ☐ Further Education (Vocational Qualifications: i.e. GNVQ/NVQ/HND)
- ☐ Higher Education (BSc/BA or equivalent)
- ☐ Postgraduate Education (MSc/MA/PhD or equivalent)

4.11 What was your relative's previous occupation?

4.12 Is your relative on AChEIs?

☐ YES

☐ NO

Check list for interviewer at close of interview

On behalf of the iCST team, please thank the participant and carer for their participation in the study.

- Please check that all 5 Questionnaire packs have been completed ☐
- Please check Carer Questionnaire Packs for missing and/or incorrectly completed items ☐
- Please ensure the participant identity number is written on the front of each Questionnaire Pack in the boxes provided ☐

Date

(Name and address of local unblind researcher)

Mental Health Sciences Unit (Bloomsbury Campus)
University College London
Room 114, Charles Bell House
67-73 Riding House Street
London W1W 7EJ

Tel
Mobile
Fax

Dear <NAME OF PARTICIPANTS>,

Individual Cognitive Stimulation Therapy (iCST) study,

Thank you for agreeing to take part in the iCST study, and for completing the questionnaires when my colleague (Local iCST blind researcher) visited you at home recently. I can now tell you that you have been allocated to the iCST group. This means that both you and the person you are caring for will be participating in the Individual Cognitive Stimulation Therapy (iCST) sessions.

(I / Local iCST unblind researcher) will be contacting you very shortly to arrange a time that is most convenient to you for a visit in order to receive one-to-one Individual Cognitive Stimulation Therapy (iCST) training in your home. This training session will prepare you to effectively and confidently deliver iCST prior to commencing the iCST sessions.

iCST will involve engaging in activities such as word games and number games with the person you are caring for. All the resources you require for the sessions will be provided in the training visit and you will receive continuous support throughout the programme (regular phone calls and visits) should you require them.

My colleague, (Local iCST blind researcher) will arrange to visit you again in 13 weeks and 26 weeks, to repeat the questionnaire process. Please remember that **it is important that you do not tell him/her that you are delivering iCST sessions**. If you need to discuss any aspect of the study, please contact me on (office number and mobile of Local iCST unblind researcher) or (email of Local unblind researcher surname@ucl.ac.uk).

Thank you again for taking part in this research study, your help is greatly appreciated.

Yours sincerely,

Name of Local iCST Unblind researcher

Date

(Name and address of local unblind researcher)

Mental Health Sciences Unit (Bloomsbury Campus)
University College London
Room 114, Charles Bell House
67-73 Riding House Street
London W1W 7EJ

Tel:
Mobile
Fax:

Dear <NAME OF PARTICIPANTS>,

Individual Cognitive Stimulation Therapy (iCST) study,

Thank you for agreeing to take part in the iCST study, and for completing the questionnaires when my colleague (Local iCST blind researcher) visited you at home recently. I am writing to inform you that you have been allocated to the control group. This means that both you and the person you are caring for will be continuing with your usual activities and not participating in the Individual Cognitive Stimulation Therapy (iCST) sessions.

However, you are an important part of the research process, so we still require you to fill out the questionnaires in 13 weeks and again in 26 weeks time. The reason we ask the same questions again is to compare the results with the group that is receiving Individual Cognitive Stimulation Therapy (iCST). When my colleague (Local iCST blind researcher) arranges to visit you again to complete the questionnaires, please remember that **it is important that you do not tell him/her that you are not participating in iCST.**

If you need to discuss any aspect of the study, please contact me on (office number and mobile of Local iCST unblind researcher) or (email of Local unblind researcher surname@ucl.ac.uk)

Thank you again for taking part in this research study, your help is greatly appreciated.

Yours sincerely,

Name of Local iCST unblind researcher

iCST: Individual Cognitive Stimulation Therapy for people with dementia

Interviewer Perception Sheet (Interviewer 1)

This sheet should be completed by project researchers conducting the first and second follow-up interviews of participants and carers. There are separate sheets for each interviewer. If only one interviewer is involved, this sheet should be left blank.

To be completed by the interviewer 1

Participant identity Number:

Centre Name:

1st Follow-up

☐

2nd Follow-up

☐

Completed by (please print name):

Signed:

Interview date:

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d	d		m	m		y	y	y	y

Who did you interview today? *Please tick one box only.*

Participant only

☐

Carer Only

☐

Participant and carer

☐

Following your interview with the participant and/or carer today, to which group in the trial do you think they have been allocated? *Please tick **one** box only.*

The participant and carer are ...

Definitely in the CONTROL Group	More likely to be in the CONTROL Group	Equally likely to be CONTROL Group or INTERVENTION Group	More likely to be in the INTERVENTION Group	Definitely in the INTERVENTION Group
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

iCST: Individual Cognitive Stimulation Therapy for people with dementia

Interviewer Perception Sheet (Interviewer 2)

This sheet should be completed by project researchers conducting the first and second follow-up interviews of participants and carers. There are separate sheets for each interviewer. If only one interviewer is involved, this sheet should be left blank.

To be completed by the interviewer 2

Participant identity Number:

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Centre Name:

1st Follow-up

☐

2nd Follow-up

☐

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Who did you interview today? *Please tick one box only.*

Participant only

☐

Carer Only

☐

Participant and carer

☐

Following your interview with the participant and/or carer today, to which group in the trial do you think they have been allocated? *Please tick one box only.*

The participant and carer are ...

**Definitely in the
CONTROL Group**

☐

**More likely to be
in the CONTROL
Group**

☐

**Equally likely to
be CONTROL
Group or
INTERVENTION
Group**

☐

**More likely to be
in the
INTERVENTION
Group**

☐

**Definitely in the
INTERVENTION
Group**

☐



iCST

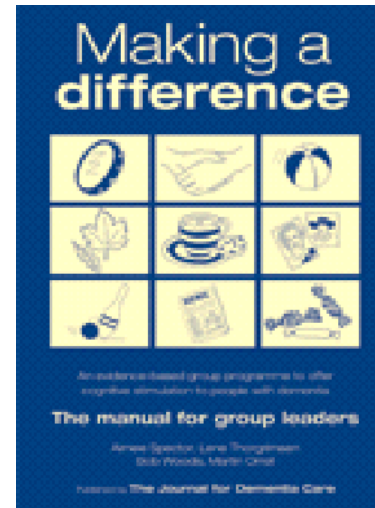
Individual Cognitive Stimulation Therapy

Background information leaflet for carers

What is CST?



- Group activity sessions for people with mild to moderate dementia
- Activities designed to be mentally stimulating and fun
- A study found that attending CST groups was beneficial for cognitive skills such as communication. Group members also reported improvements in quality of life
- Extended programme of CST developed – Maintenance CST

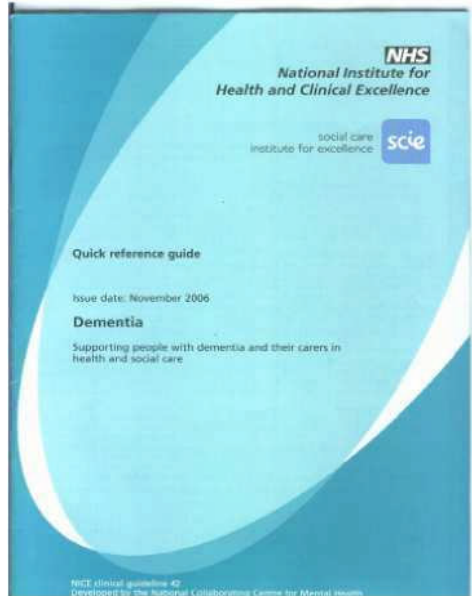


Notes:

NICE-SCIE guidelines (2006)



The National Institute of Clinical Excellence is a health authority that recommends which treatments people should receive.



'People with mild/moderate dementia of all types should be given the opportunity to participate in a structured group cognitive stimulation programme ... provided by workers with training and supervision ... irrespective of any anti-dementia drug received ...'

Notes:

What is the iCST programme?



- Home based activity programme for carers and people with dementia
- Activities mentally stimulating and enjoyable
- 3 sessions per week
- Each session should last 20-30 minutes
- Research programme is 25 weeks long
- Themed activities eg: word games, art discussion, current affairs discussion



Notes:

Session structure



1. Discussion of the day, date, weather, location (5 mins)
2. Discussion of events in the news or current issues (5 mins)
3. Main activity (20 mins)



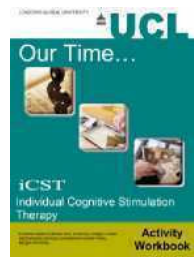
Notes:

What resources will I receive?



iCST Manual:

- First point of call when preparing for a session
- How-to guide to iCST
- Outlines theme and structure for each session



Activity Workbook:

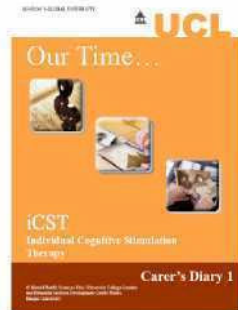
- All paper based resources for activities suggested in the Manual
- Page numbers for paper based resources can be found in the iCST Manual

iCST Toolkit:

- Extra resources eg: boules, cards

Notes:

What is the Carer's Diary?



- Use the diary to tell us how your sessions went
- Page for each theme (2 sessions)
- Rate session for person's enjoyment, interest, communication and mood
- Box to write any extra comments about the sessions



- Carer's Diary 1 will be collected half way through the programme by your supporting researcher. During this support visit you will receive Carer's Diary 2. If you have not completed Diary 1, you will be given another copy to use.
- Carer's Diary 2 will be collected at the end of the programme

Notes:

Key principles of iCST



1	Person centred approach
2	Offering choice
3	Focusing on opinions rather than facts
4	Using reminiscence
5	Always have a tangible focus – something to look at, touch, or feel
6	Maximising potential
7	Enjoyment and fun
8	Stimulating language
9	Strengthening the caregiving relationship

Notes:

Role playing exercise



Imagine you are a person with Dementia, and the researcher is your carer. You will now spend some time going through a session together in 2 role playing exercises.

Keep the following points in mind during exercise 1:

- Did you notice any **'bad' practice** from your carer?
- Could your carer have done anything differently during the session?

Keep the following points in mind during exercise 2:

- Did you notice any **'good' practice** from your carer?
- How did your carer use the materials she / he had?



Notes:

Your supporting researcher is:

will provide advice and support for you
and your friend / relative during the study.

You can contact them on:

Telephone: _____
Mobile: _____
Email: _____

Putting the key principles into practice

How will the key principles help me with iCST sessions?

The key principles are here to help you and your relative/friend get the most out of this programme, so it is important that you feel ready to put them into practice. Take some time to read the following pages before you begin, and feel free to revisit them during the programme. The principles are grouped according to when and how you can use them in the session.

Choosing activities:

Choice

This programme is **not prescriptive**. In the Manual there are a range of different themes but you can tailor the programme to your friend / relative's interests by coming up with your own ideas for activities or using your own resources.

How do I make sure activities are stimulating?

A stimulating activity will get your relative/friend thinking and encourage them to explore ideas.

Activities are categorised into **Level A** and **Level B**. Level B activities tend to be more challenging than Level A activities. Choose the one you think will be engaging but take care to ensure the activity is not so difficult the person feels deskilled.

You do not need to stick to the same 'level' for the duration of the programme, mix and match according to the person's skills and interests.

? Problem Solving

What if the person seems to be struggling with the activity I have chosen?

- Some sessions will be more challenging than others, especially since people have different interests and skills.
- If the person asks why things are difficult or seems to be anxious, let them know that you are trying to get them to exercise skills that have not been used for a while, and stimulate different parts of the brain.
- Try a different activity if you have time.
- If the person is distressed, do not continue with the activity. Try to end on a good note by doing something you know they enjoy instead.

Maximising Potential

Be careful not to assume the person is unable to contribute or carry out an activity simply because they were not able to yesterday or last week. People with dementia often function at less than their full potential, perhaps due to lack of stimulation or opportunity.



Tips:

- Keep an **open mind** when choosing activities
- Give the person **time** to gather their thoughts or carry out an activity
- **Do not overload or overwhelm** them with information
- Provide just enough **prompting** to enable the person to do the activity themselves

Prompting discussion:

Stimulating language and discussion

Often with people with dementia, we tend to talk about things from the past. Whilst this is enjoyable for people, it often involves recalling information, which has been over-rehearsed. The aim of iCST is to continually encourage new ideas, thoughts and associations, rather than just recall previously learned information.

How do I encourage discussion?

- 1) **By asking questions:** The way you phrase questions is important in encouraging the person to explore ideas. Here are some examples:

What do these
have in
common?

What do you
think about....?

How are these
different?

- 2) **By introducing a variety of topics:** Rather than introducing topics likely to have been discussed before, e.g.: "What do you think of the Royal family?", encourage discussions about new topics such as "Is modern art really art?" or "What do you think of same sex weddings?" In discussion based activities, you will be provided with examples of discussion topics to give you ideas.

Using reminiscence

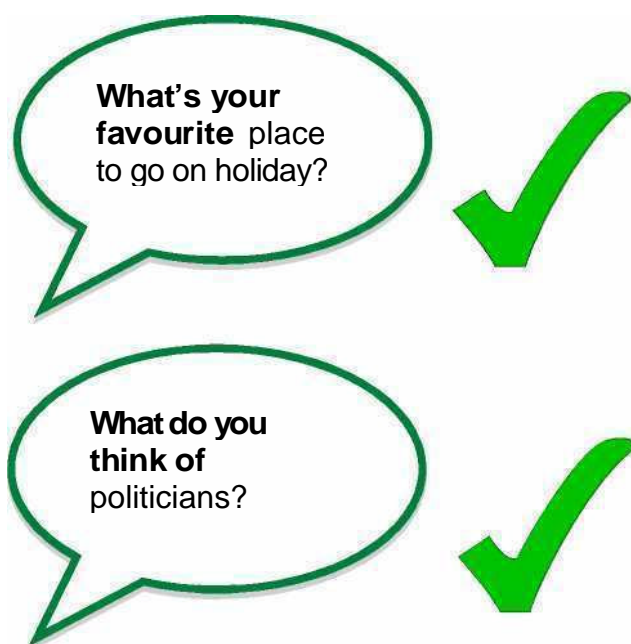
Using past memories is an excellent way of tapping into a strength that many people with dementia have, in terms of recalling experiences from much earlier in their lives. Remember though that some people may have unhappy (even traumatic) memories of their earlier life, and some sensitivity is needed. Reminiscence can also be a useful tool towards orientation, which is a key goal of iCST. Many iCST sessions allow you to compare old and new, thinking about how things have changed over time.

Asking questions:

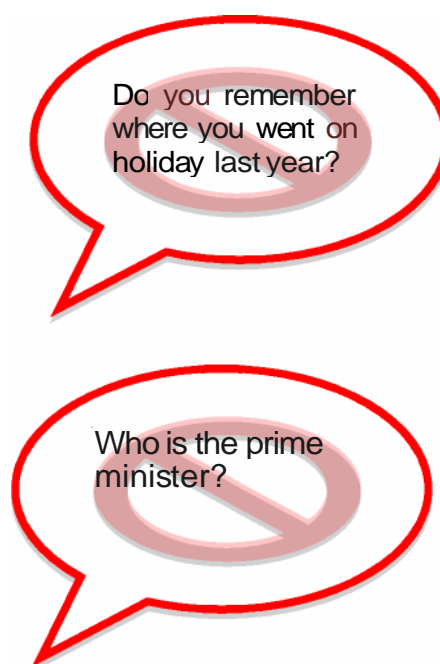
Opinions rather than facts

In iCST sessions, we need to focus on the person's strengths. **If we focus on 'facts' too much, there is the risk that the person will often be wrong.** If we ask the person for their opinions they cannot be wrong. **The way you ask questions is key to ensuring you do not put the person on the spot** by focusing on facts. Here are some examples:

Opinion based questions



Fact based questions



At first making sure you ask questions in this way might feel challenging, but with practice it will become second nature.

Tips:

- Jot down some opinion based questions and have them to hand during the session.
- If the person offers fact based information of their own accord during discussions (e.g.: "I remember when I learnt to ride a bike when I was 5", "That's the Eiffel Tower in the picture" etc.) this is great. The main thing is not to ask your friend / relative direct questions with the intention of getting this information.
- If there is a fact based element to any of the activities, give the person a selection of options to choose from or cues such as images to help them find the answer.



? Problem Solving:

The person said something I know is not right, what do I do?

It doesn't matter whether the person offers comments that you know are not right or 'not true'. There is no need to correct them, just move on to the next question or topic. Answers have been provided for activities in the Activity Workbook, but there is no need to 'mark' responses. They are simply there for you to look at if you wish, or if the person requests the answer to a question. Most of the activities are designed to be 'open' with several possible answers.

Supporting the person during the session:

Person centered

We need to **see the person first and foremost**, rather than focusing on the dementia and the associated impairments. Ask yourself about the person's **strengths**, and think about how you can incorporate their interests into the sessions, rather than concentrating on their areas of difficulty.

Always have a tangible focus – something to look at, touch or feel

Multi-sensory cues are really important, as memory works much better if you do not rely on just one sense. Try to have a mix of activities involving vision, touch, hearing, taste and smell. Often it is a combination of senses that is most effective.



Tip: Having something to look at or touch really helps aid concentration. Words in a discussion may soon be lost when memory is limited; having the object, a photograph or picture keeps the person's attention on the activity.

Strengthening the caregiving relationship

The activities present a great opportunity for you and your relative / friend to enjoy some quality time together.

Carer Questionnaire Set up

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

Carer Questionnaire

This booklet of questionnaires should be completed via self-report by the carer delivering the iCST Treatment.

General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which time point is this? *Please tick **one** box only.*

Set-up visit

☐

1st Monitoring Visit

☐

(Week 12 of iCST Treatment)

2nd Monitoring Visit

☐

(Week 25 of iCST Treatment)

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Carer Questionnaire Set up

This questionnaire asks about your views in delivering Individual Cognitive Stimulation Therapy. For each of the following questions, please place a tick in the box that best describes your answer. *Please tick **one** box for **each** item.*

Set-up Visit

1. In general, how would you rate your knowledge of Individual Cognitive Stimulation Therapy? (please tick one box):

My knowledge of Individual Cognitive Stimulation Therapy is:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. How would you rate your confidence in delivering the individual cognitive stimulation sessions? (please tick one box):

Very little	Fair	Good	Very confident
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How much support will you need by the research team in delivering the individual cognitive stimulation sessions? (please tick one box):

Not at all	A little	Quite a lot	A lot
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Will you require weekly telephone support in delivering the iCST sessions? (please tick one box):

I would prefer weekly telephone support ☐
I would prefer to receive telephone support once or twice per month ☐

Please indicate your response to the following statement:

5. "My relative and I will be able to engage successfully in the individual cognitive stimulation sessions"? (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Carer Questionnaire Set up

We would greatly appreciate comments that carers may have about Individual Cognitive Stimulation Therapy, which will help us improve the intervention in the future. You can use the section below to provide your feedback. Thank you for your time in completing this questionnaire.

Adherence Questionnaire Researcher Setup

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment.

General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

To be completed by the interviewer																					
Participant Identity Number:	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																				
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Adherence Questionnaire

Researcher Setup

Note to Interviewer: The following questions should be completed by the unblind researcher during and after the iCST Set-up Visit.

A. Section 1 Set-up Visit (Visit 1)

1. Has the family carer been trained to use iCST?

YES

☐

NO

☐

If no please state the reason

2. Please report the date of iCST training for the family carer

 / /

3. Please report the date of the set-up visit

 / /

4. Please report the start date of the iCST treatment (the date when the first iCST session was completed)

 / /

5. Please indicate the duration of the set-up visit (in minutes and hours)

----- (hours)

----- (minutes)

It is recommended that the unblind researcher observes the first iCST session run by the family carer (and provides additional help if required).

6. In general, how would you rate the success of the first session of the set-up visit? (please tick one box):

Excellent

☐

Very good

☐

Good

☐

Fair

☐

Poor

☐

Please complete the items below in terms of carer's ability/confidence and amount of support they will need during the intervention:

7. The carer will be able to engage successfully with the person with dementia in the iCST sessions (please tick one box):

A lot

☐

Quite a bit

☐

A little

☐

Not at all

☐

Adherence Questionnaire Researcher Setup

8. Please rate the amount of support the carer will need in delivering the iCST sessions (please tick one box):

A lot

Quite a bit

A little

Not at all

9. Will the intervention be delivered (mostly) by the (primary) family carer?

☐ YES

☐ NO *if no go to question 10*

10. If no please indicate below who will deliver most of the iCST sessions:

☐ Other family member

Please specify _____

☐ Other (i.e. friend, neighbour)

Please specify _____

☐ Paid carer visiting participant

Please specify _____

☐ Member of staff (Voluntary Sector)

Please specify _____

☐ Member of staff (NHS, Local Services)

Please specify _____

☐ Member of staff (Private sector)

Please specify _____

☐ Unknown

Please report any additional comments/observations

[illegible]

Our Time...



iCST

Individual Cognitive Stimulation Therapy

Carer's Diary 1





iCST

Carer's Diary 1

Calendar 2012 2

Calendar 2013 4

iCST Manual Section 1: Sessions 1-12 6

iCST Manual Section 2: Sessions 13-26 12

iCST Manual Section 3: Sessions 25-32 18

Our Time...



January

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August

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September

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1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

How was your session today?

MY LIFE: Sessions 1 & 2

Part 1 completed

Yes ☐

No ☐

Part 2 completed

Yes ☐

No ☐



Date:

Date:

Please circle the appropriate response

	Not at all	A little	Quite a lot	Very much	Extremely
Did the person show interest?	1	2	3	4	5
Did the person communicate?	1	2	3	4	5
Did the person show enjoyment?	1	2	3	4	5
How would you rate the person's mood today?	Poor	Fair	Good	Very good	Excellent

Comments

.....

.....

.....

.....

How was your session today?

CURRENT AFFAIRS: Sessions 3 & 4

Part 1 completed

Yes ☐ No ☐

Part 2 completed

Yes ☐ No ☐

Date: Date:



Please circle the appropriate response

	Not at all	A little	Quite a lot	Very much	Extremely
Did the person show interest?	1	2	3	4	5
Did the person communicate?	1	2	3	4	5
Did the person show enjoyment?	1	2	3	4	5
How would you rate the person's mood today?	Poor	Fair	Good	Very good	Excellent

Comments

.....

.....

.....

.....

Telephone contact Adherence Questionnaire

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment.

General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which time point is this? *Please tick **one** box only.*

Set-up visit

☐

Telephone Contact

☐

(Number: . Week of iCST Treatment)

Monitoring Visit

☐

(Number: . Week of iCST Treatment)

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Telephone contact Adherence Questionnaire

Note to Interviewer: The following questions should be completed by the unblind researcher during Telephone Contacts with the family carer.

Telephone Contact _____ (which scheduled call)

1. Was Telephone Contact made?

☐ YES ☐ NO

If no please indicate why the telephone contact did not take place

2. Please report the date of Telephone Contact

/ /

3. How many minutes/hours did the telephone contact last?

----- (hours)
----- (minutes)

4. On average how many sessions per week did the carer and participant report completing?

- ☐ 0 sessions
☐ 1 session
☐ 2 sessions
☐ 3 sessions
☐ Other please specify -----

5. How long does one iCST session last on average (one session only) according to the family carer?

----- (minutes)

6. How long does the carer spend on average in preparing for the iCST sessions (one session only)?

----- (minutes)

7. Is the intervention delivered (mostly) by the (primary) family carer?

☐ YES ☐ NO *if no go to question 8*

8. If no please indicate below who delivers most of the iCST sessions:

- ☐ Other family member
Please specify _____
☐ Other (i.e. friend, neighbour)
Please specify _____
☐ Paid carer visiting participant
Please specify _____

Telephone contact Adherence Questionnaire

☐ Member of staff (Voluntary Sector)

Please specify _____

☐ Member of staff (NHS, Local Services)

Please specify _____

☐ Member of staff (Private sector)

Please specify _____

☐ No-one (participant and carer dropped out)

☐ Unknown

9. Has the family carer stopped providing the iCST sessions?

☐ YES

☐ NO

10. Has the carer reported any difficulties running the iCST sessions or reasons why (some/all) sessions were not completed?

☐ YES

☐ NO

11. Please indicate below any areas of difficulties reported by the carer that has resulted in not providing (all or some) of the iCST sessions (*tick **all** that apply*)

☐ Patient ill health

☐ Carer ill health

☐ Patient is not enjoying the sessions

☐ Carer is not enjoying the sessions

☐ Patient not able to participate due to stress, anxiety, mood etc.

☐ Carer not able to participate due to stress, anxiety, burden etc.

☐ Holidays/Family commitments

☐ Work commitments for carer

☐ The carer is experiencing difficulties in running the sessions

☐ Patient does not want to take part in the sessions

☐ Carer can not find free time to deliver the sessions

☐ Difficulties with the Manual and Activities

☐ Other please specify _____

☐ Unknown

1. Has there been any 'out of protocol' telephone contact with the family carer?

☐ YES

☐ NO

☐ ☐ Number of telephone calls

1. Telephone Call 1 Lasting _____ minutes

2. Telephone Call 2 Lasting _____ minutes

3. Telephone Call 3 Lasting _____ minutes

4. Telephone Call 4 Lasting _____ minutes

5. Telephone Call 5 Lasting _____ minutes

Telephone contact Adherence Questionnaire

Please report details of any 'out of protocol' contact

This image shows a full page of primary-ruled paper. It features multiple sets of horizontal dashed lines spaced evenly down the page, providing a guide for handwriting practice. The lines are black and set against a white background. There are no margins, text, or other markings on the page.

Please report any additional comments/observations

This image shows a full page of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

Carer Monitoring Questionnaire

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed via self-report by the carer delivering the iCST Treatment.

General Instructions

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which time point is this? *Please tick **one** box only.*

Set-up visit

☐

1st Monitoring Visit

☐

(Week 12 of iCST Treatment)

2nd Monitoring Visit

☐

(Week 25 of iCST Treatment)

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Carer Monitoring Questionnaire

The questionnaire below asks about your views in delivering Individual Cognitive Stimulation Therapy. For each of the following questions, please place a tick in the box that best describes your answer. *Please tick **one box** for **each** item.*

Monitoring Visit _____

1. I have been able to focus on opinions rather than facts during the individual cognitive stimulation sessions (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. I have been able to develop ideas in a sensitive manner during the individual cognitive stimulation sessions (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. I have incorporated my relative's personal interests in the activities (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. I have been able to adapt the sessions to accommodate my relative's abilities (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate your response to the following statement:

5. "My relative and I have been able to engage successfully in the individual cognitive stimulation sessions"? (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Carer Monitoring Questionnaire

6. In general, how would you rate your knowledge of Individual Cognitive Stimulation Therapy? (please tick one box):

My knowledge of Individual Cognitive Stimulation Therapy is:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. How would you rate your confidence in delivering the individual cognitive stimulation sessions? (please tick one box):

Very little	Fair	Good	Very confident
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. How would you rate the support you have received so far in delivering the individual cognitive stimulation sessions? (please tick one box):

I would rate the support I have received as:

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Carer Monitoring Questionnaire

We would greatly appreciate comments that carers may have about Individual Cognitive Stimulation Therapy, which will help us improve the intervention in the future. You can use the section below to provide your feedback. Thank you for your time in completing this questionnaire.

Adherence Questionnaire

Monitoring researcher

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment.

General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which time point is this? *Please tick **one** box only.*

Set-up visit

☐

Telephone Contact

☐

(Number: . Week of iCST Treatment)

Monitoring Visit

☐

(Number: . Week of iCST Treatment)

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Adherence Questionnaire

Monitoring researcher

Note to Interviewer: The following questions should be completed by the unblind researcher during and after the iCST Monitoring Visit.

Monitoring Visit _____

1. Did the Monitoring Visit take place?

YES

☐

NO

☐

If no please state the reason

2. Please report the date of the Monitoring Visit

 / /

3. Please indicate the duration of the Monitoring Visit

----- (hours)

----- (minutes)

Please complete the items below in terms of carer's ability/confidence and amount of support received during the intervention:

4. Has the carer been able to engage successfully with the person with dementia in the iCST sessions? (please tick one box):

A lot

☐

Quite a bit

☐

A little

☐

Not at all

☐

5. Please rate the amount of support the carer has received in delivering the iCST sessions? (please tick one box):

A lot

☐

Quite a bit

☐

A little

☐

Not at all

☐

6. Is the intervention delivered (mostly) by the (primary) family carer?

☐ YES

☐ NO *if no go to question 7*

7. If no please indicate below who is delivering most of the iCST sessions:

☐ Other family member

Please specify _____

☐ Other (i.e. friend, neighbour)

Please specify _____

☐ Paid carer visiting participant

Please specify _____

☐ Member of staff (Voluntary Sector)

Please specify _____

Adherence Questionnaire

Monitoring researcher

☐ Member of staff (NHS, Local Services)

Please specify _____

☐ Member of staff (Private sector)

Please specify _____

☐ No-one (participant and carer dropped out)

☐ Unknown

Please note that during this visit the unblind researcher should collect the Diary Sheets that have been completed by the family carer.

8. How many iCST sessions has the carer and person with dementia completed (indicate full amount of sessions as reported in Carer's Diary)

Treatment Adherence Point _____

----- (sessions)

9. Has the family carer stopped delivering the iCST sessions?

☐ YES

☐ NO

10. Has the carer reported any difficulties running the iCST sessions or reasons why (some/all) sessions were not completed?

☐ YES

☐ NO

11. Please indicate below any areas of difficulties reported by the carer that has resulted in not providing all or some of the sessions (*tick **all** that apply*)

☐ Patient ill health

☐ Carer ill health

☐ Patient is not enjoying the sessions

☐ Carer is not enjoying the sessions

☐ Patient not able to participate due to stress, anxiety, mood etc.

☐ Carer not able to participate due to stress, anxiety, burden etc.

☐ Holidays/Family commitments

☐ Work commitments for carer

☐ The carer is experiencing difficulties in running the sessions

☐ Patient does not want to take part in the sessions

☐ Carer cannot find free time to deliver the sessions

☐ Difficulties with the Manual and Activities

☐ Other please specify _____

☐ Unknown

12. Has there been any 'out of protocol' telephone contact with the family carer?

☐ YES

☐ NO

☐ ☐ Number of telephone calls

1. Telephone Call 1 Lasting _____ minutes/hours

2. Telephone Call 2 Lasting _____ minutes/hours

Adherence Questionnaire

Monitoring researcher

3. Telephone Call 3 Lasting _____minutes/hours

4. Telephone Call 4 Lasting _____minutes/hours

5. Telephone Call 5 Lasting _____ minutes/hours

Please report details of any 'out of protocol' contact

This image shows a full page of white paper with horizontal black ruling lines. The lines are evenly spaced and run across the width of the page, providing a template for handwriting practice or general writing. There are no margins, text, or other markings on the page.

Please report any additional comments/observations

This image shows a full page of a document template designed for handwritten notes or essays. It features approximately 28 evenly spaced horizontal black lines across the entire width of the page. The lines are thin and consistent in thickness, providing a guide for writing without being distracting. There are no margins, headers, footers, or other markings present on the page.

Carer Additional Support Visit

--

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment when visiting the family carer on out of protocol visit(s). Please use a photocopy of this form.

General Instructions

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which Additional Support Visit is this?

☐

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Carer Additional Support Visit

Note to Interviewer: The following questions should be completed by the unblind researcher during and after the iCST Monitoring Visit.

1. Please indicate the duration of the Additional Support Visit

----- (hours)

----- (minutes)

2. What is the purpose of this visit?

☐ Additional Carer Support

☐ Training for setup if skipped during setup visit. Please complete the setup questionnaire in addition

☐ Other _____

3. Has the family carer stopped delivering the iCST sessions?

☐ YES

☐ NO

4. Please indicate below the reason that the carer has requested an additional support visit (*tick **all** that apply*)

☐ Patient ill health

☐ Carer ill health

☐ Patient is not enjoying the sessions

☐ Carer is not enjoying the sessions

☐ Patient not able to participate due to stress, anxiety, mood etc.

☐ Carer not able to participate due to stress, anxiety, burden etc.

☐ Holidays/Family commitments

☐ Work commitments for carer

☐ The carer is experiencing difficulties in running the sessions

☐ Difficulties with the Manual and Activities

☐ The carer is not confident delivering the sessions

☐ Other please specify _____

☐ Unknown

5. Has the carer been able to engage successfully with the person with dementia in the iCST sessions? (please tick one box):

A lot

Quite a bit

A little

Not at all

6. Please rate the amount of support the carer has received in delivering the iCST sessions? (please tick one box):

A lot

Quite a bit

A little

Not at all

Carer Additional Support Visit

Please report any additional comments/observations

UCL, Mental Health Sciences Unit
(Bloomsbury Campus)
67-73 Riding House Street
2nd Floor, Charles Bell House
London W1W 7EJ
Phone@ +44 (0)20 7679 9452
Fax: +44 (0)20 7679 9426

GENERAL PRACTITIONER INFORMATION SHEET

Title: Individualised Cognitive Stimulation Therapy (iCST) for people with dementia

..... (Dob)..... has been invited and consented to take part in a research study. Please let us know if there is anything that is not clear, or if you would like more information.

Professor Martin Orrell runs this project from North East London NHS Foundation Trust (NELFT).

Cognitive Stimulation Therapy (CST) groups are an enjoyable and beneficial therapy for people with dementia, recommended by the NICE (2007) guidelines. They aim to keep the mind active through enjoyable activities, which are undertaken as a structured programme facilitated by experienced and trained staff. However, many people do not have access to, or are not suited to group treatment. Therefore, this study will evaluate the impact of carer-led, individualized CST (iCST) on cognition and quality of life for people with dementia. It will involve three weekly sessions for 25 weeks, covering similar themes to group CST (for example physical games, discussion of current affairs, sounds, food, word and number games). Carers will receive training and ongoing support in order to deliver the intervention effectively. It is a randomized controlled trial, therefore half the people participating will be allocated to a 'no treatment' control group, and will just be required to complete the assessment interview.

These assessments will be conducted prior to the intervention and then after 13 and then 26 weeks. They will include outcome measures looking at:

- Personal details (age, relationship, medication, educational level, etc.)
- Quality-of-life (for both the person and their carer)
- Cognition
- Depression
- Activities of daily living and behaviour
- Carer mental health

The study will **not** affect your patient's current or future treatment.

The results of this study are expected to be published in relevant journals and at conferences. All interviews are confidential and will not be disclosed to anyone else. The information collected in the study will be anonymous and patients will not be identified in any report/publication.

All proposals for research using human subjects are reviewed by the local Ethics Committee before they can proceed and the appropriate permission.

Thank you for reading this information sheet. Please do not hesitate to contact Prof Orrell if you need any further information.

Kind regards,

Research Assistant

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

Participant's GP Details

This sheet should be completed by project researchers conducting the baseline interviews of participants. This form should be retained by the centre and not forwarded to the trial co-ordinating centre.

To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--

Centre Name:

Completed by (please print name):

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Name of Doctor:

Practice Name:

Address:

Notes:

Reporting Serious Adverse Events in iCST

Instructions

1. Upon becoming aware of an adverse event involving a participant or carer, determine whether it is “serious” by examining the criteria below.

A Serious Adverse Event (SAE) is an untoward occurrence experienced by either a participant or carer which:

- a) results in death;
- b) is life-threatening;
- c) requires hospitalisation or prolongation of existing hospitalisation;
- d) results in persistent or significant disability or incapacity;
- e) is otherwise considered medically significant by the investigator.

In addition, any cases where action has been taken under the iCST protocol for the protection of vulnerable adults (dealing with suspected abuse or neglect of participants) should be reported to the London centre using this procedure.

2. If a Serious Adverse Event is deemed to have taken place, please complete the attached form and forward it to the London centre as instructed therein.

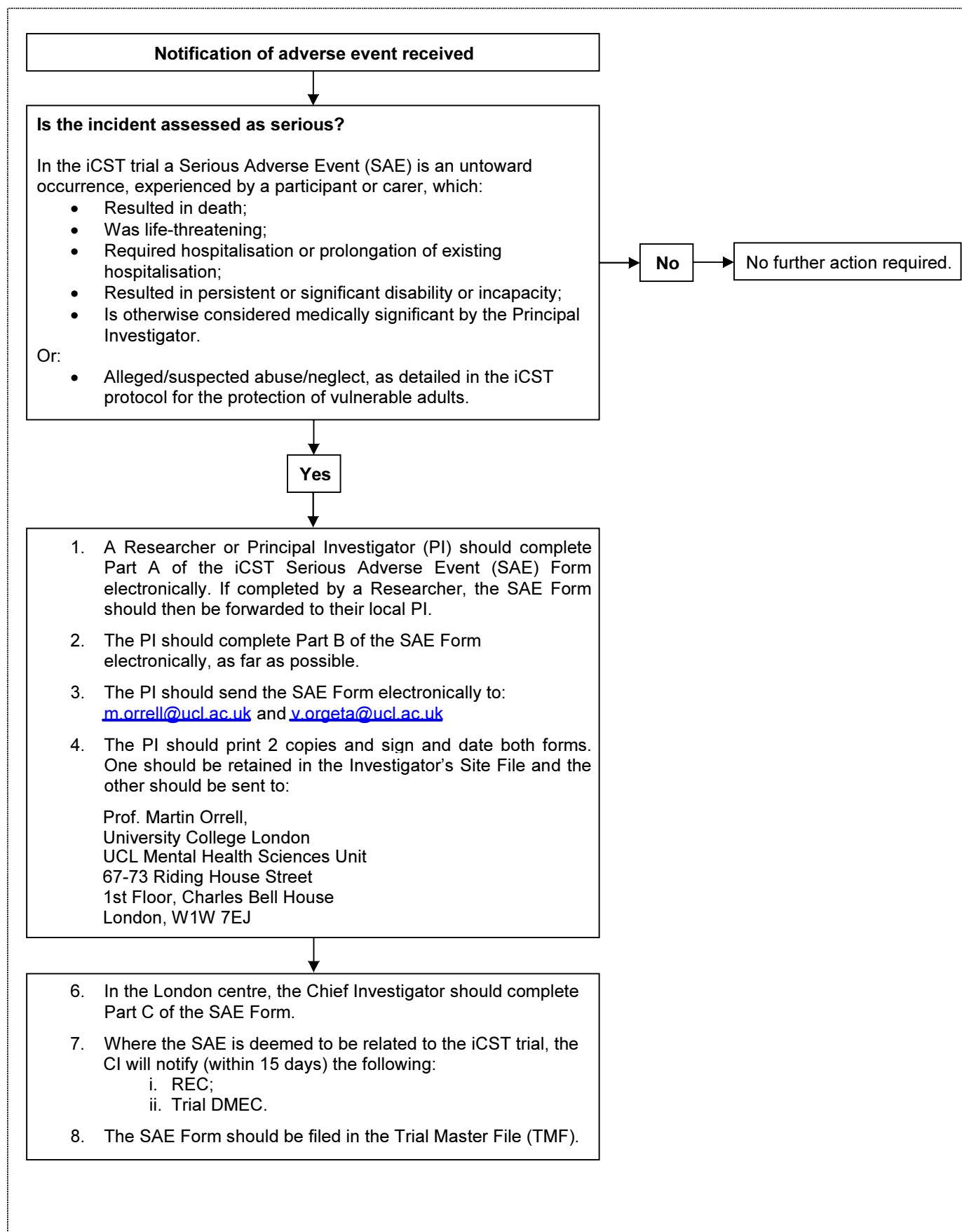
It should be noted that all Serious Adverse Events should be reported to the London centre, even if initially there may be no obvious connection to the trial. In particular:

All deaths of participants and carers should be reported to the London Centre.

All incidents of hospitalisation (and prolongation of hospitalisation) for participants and carers should be reported to the London centre (even when the illness or condition being treated has no connection to the trial).

3. The iCST Data Ethics and Monitoring Committee (DMEC) has specifically requested that, as far as possible, all hospitalisations are recorded. Researchers undertaking follow-up assessments (this does not apply to baseline assessments) should, therefore, consider this when completing questionnaire booklet QB6 (Service Use). A SAE form should be completed where the participant or carer has indicated that they have stayed in hospital and this has not already been reported to the research team.

Figure 1. – Flow chart of iCST Serious Adverse Event Reporting Procedure



iCST Serious Adverse Event Reporting Form

PART A (to be completed by Researcher or Principal Investigator)

A1. Centre Name:

Completed by:

A2. Date form completed:

A3. Participant Identity (Trial) Number

--	--	--	--	--	--

A4. How did the centre become aware of this incident?

A5. Was this SAE suffered by the participant or carer? *Please place an "x" in **one** box only.*

Participant ☐

7

Carer ☐

1

A6. Are you reporting a death? Please place an "x" in **one** box only.

Yes ☐ Please proceed to **Question A8**

7

No ☐ Please proceed to **Question A7**

7

A7. Please categorise this event, by placing an “x” in all appropriate options.

- ☐ Life threatening
- ☐ Hospitalisation or prolongation of existing hospitalisation
- ☐ Persistent or significant disability or incapacity
- ☐ Otherwise considered medically significant by the investigator
- ☐ Alleged/suspected abuse/neglect, as detailed in protection of vulnerable adults protocol

A8. Date of SAE:

A9. Location of SAE:

A10. Describe the circumstances of the event. Is there any evidence that participation in the trial may have been a contributing factor?

(Attach further sheets if necessary)

[illegible]

PART B (to be completed by Principal Investigator)

B1. In your opinion, did this SAE arise as a result of the participant's or carer's involvement in the iCST trial? Please place an "x" in **one** box only.

Yes

☐

No

☐

B2. Please add any comments regarding the SAE.

Please complete the details below:

B3. Name of PI:

Please send an electronic version to m.orrell@ucl.ac.uk and v.orgeta@ucl.ac.uk

B4. Signature of PI:

B5. Date of signature:

/

/

d

d

m

m

y

y

y

y

Please print two copies. After signature, please send by post to the address below and retain a copy for the Investigator's Site File.

Prof. Martin Orrell,
University College London
UCL Mental Health Sciences Unit
67-73 Riding House Street
1st Floor, Charles Bell House
London, W1W 7EJ

PART C (to be completed by Chief Investigator)

C1. Action taken:

C2. Name of CI:

Prof. Martin Orrell

C3. Signature of CI:

C4. Date of signature:

/

/

d

d

m

m

y

y

y

y

INFORMATION SHEET FOR CARERS: INDIVIDUAL QUALITATIVE INTERVIEWS

Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

Why have I been chosen to participate in the interview?

You are being invited to take part in the interview because you have just completed the individual Cognitive Stimulation Therapy (individual CST). The following information is for you to understand why the interview is taken place and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the interview?

The purpose of the interview is for you to express your experience, thoughts and views about the iCST intervention. This additional data we will provide us with further feedback about the programme from those who were involved in the treatment and have completed the trial.

Will my taking part in the study be kept confidential?

The interview will be audio recorded, so may I take the opportunity to check that this is fine for you. Any information which you provide during the interview will be kept strictly confidential. All data is stored without any identifying details under secure conditions. If you wish that the interview was not recorded, then no audio recording will take place at any part of the interview.

What will happen if I don't want to take part in the interview?

It is one off interview. You will be free to withdraw from the interview at any time without giving a reason. Withdrawing from the interview will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

What will happen to the results of the research?

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the East London 3 Ethics Committee.

Who can I contact for further information?

For more information about this interview, please contact:

Phuong Leung
University College London
Charles Bell House
67-73 Riding House Street, London, W1W 7EJ.
Phone: 020 7679 9023 Mobile: 0795151945.
Email: phuong.leung@ucl.ac.uk

Or if you have any complaints about this study please contact:

Fiona Horton R&D Administrator
R& D Department, NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB
Phone 0844 600 1200 Ext 4485
Fax 0844 493 0289

Email: Fiona.Horton@nelft.nhs.uk

Thank you for taking part in the interview!

INFORMATION SHEET FOR PARTICIPANTS: INDIVIDUAL QUALITATIVE INTERVIEW

Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

Why have I been chosen to participate in the interview?

You are being invited to take part in the interview because you have just completed the individual Cognitive Stimulation Therapy (individual CST) intervention. The following information is for you to understand why the interview is taken place and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the interview?

The purpose of the interview is for you to express your experience, thoughts and views about the iCST intervention. This additional data will provide us with further feedback about the programme from those who were involved in the treatment and have completed the trial.

Will my taking part in the study be kept confidential?

The interview will be audio recorded, so may I take the opportunity to check that this is fine with you. Any information which you provide during the interview will be kept strictly confidential. All data is stored without any identifying details under secure conditions. If you wish that the interview was not recorded, then no audio recording will take place at any part of the interview.

What will happen if I don't want to take part in the interview?

It is one off interview. You will be free to withdraw from the interview at any time without giving a reason. Withdrawing from the interview will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

What will happen to the results of the research?

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

Who has reviewed the study?

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the East London 3 Ethics Committee.

Who can I contact for further information?

For more information about this interview, please contact:

Phuong Leung
University College London
Charles Bell House
67-73 Riding House Street, London, W1W 7EJ.
Phone: 020 7679 9023 Mobile: 0795151945.
Email: phuong.leung@ucl.ac.uk

Or if you have any complaints about this study please contact:

Fiona Horton R&D Administrator
R& D Department, NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB
Phone 0844 600 1200 Ext 4485
Fax 0844 493 0289

Email: Fiona.Horton@nelft.nhs.uk

Thank you for taking part in the interview!

Caregiver Consent Form (MCA) – Qualitative interview.

Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia

Name of Researcher:.....

Please Initial Boxes

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or my relative being affected.

3. I understand that all information given by me about me will be treated as confidential by the research team.

4. I agree to take part in the above interview.

Name of Caregiver

Date

Signature

Name of relative / friend

**Name of Person taking consent
(if different from the researcher)**

Date

Signature

Researcher

Date

Signature

**Participant Consent Form (MCA) – Individual Interviews
Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia**

Name of Researcher:.....

Please Initial Boxes

1. I confirm that I have read and understand the information sheet for the above interview and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.
3. I understand that all information given by me or about me will be treated as confidential by the research team.
4. I agree to take part in the above interview.

Name of Participant

Date

Signature

Name of Person taking consent
(if different from the researcher)

Date

Signature

Researcher

Date

Signature

Name of carer

Date

Signature

University College London,
Charles Bell House,
67-73 Riding House Street,
London, W1W 7EJ.
Tel:
Mobile:
Email:

Date:

Individual Cognitive Stimulation Therapy (iCST) for Dementia

Dear <name of carer>,

Thank you for agreeing to take part in the interview. On the phone we agreed that I would be visiting you at the following time/date:

If this does not sound right or you discover that you cannot manage at this time or date please phone me on 0795151945. You can record a message if I'm not available to answer the phone.

Some more information about the interview

The purpose of the interview is for both people with dementia and their carers who have completed the iCST trial – treatment group to express their experience, thoughts and views about the iCST and whether it has been beneficial to them. This is a one off interview and might take up one hour.

If you have any questions please feel free to give me a phone, or ask at the interview session.

Thank you very much for agreeing to take part, your participation is greatly appreciated.

I'm looking forward to meeting you.

Best wishes,

<name of researcher>

Chapter 4: Qualitative data analysis using Nvivo

A work sample of running a text search query in Nvivo

<Internals\BEH Interview 1> - § 7 references coded [0.18% Coverage]

Reference 1 - 0.03% Coverage

Whereas doing it **together** we can, well, prompt each

Reference 2 - 0.03% Coverage

got a bit more time **together** than we did have because

Reference 3 - 0.03% Coverage

time that we are spending **together** really. And we have a

Reference 4 - 0.03% Coverage

we try to do them **together**. So I think it... yes

Reference 5 - 0.03% Coverage

mean we talked about it **together** and I recorded it.

Reference 6 - 0.03% Coverage

diary has two sets merged **together**, or it is fine as

Reference 7 - 0.03% Coverage

that we have gone on **together** would not have happened at

<Internals\BEH Interview 10> - § 10 references coded [0.19% Coverage]

Reference 1 - 0.02% Coverage

you see, because we live **together**, and we share so much

Reference 2 - 0.02% Coverage

do that because we live **together**, we watch the news together

Reference 3 - 0.02% Coverage

together, we watch the news **together**, we do a lot together

Reference 4 - 0.02% Coverage

together, we do a lot together anyway, so that part of

Reference 5 - 0.02% Coverage

while but we haven't lived together like this ever in our

Reference 6 - 0.02% Coverage

was glad of the time together but I didn't honestly find

Reference 7 - 0.02% Coverage

something and work on it together for 40 minutes or something

Reference 8 - 0.02% Coverage

you from doing the activity together?

Reference 9 - 0.02% Coverage

was being able to get together to do them, you know

Reference 10 - 0.02% Coverage

we can look at it together but we don't have a

<Internals\BEH Interview 2> - § 1 reference coded [0.02% Coverage]

Reference 1 - 0.02% Coverage

her when we have tea together so again that is another

<Internals\BEH interview 5> - § 6 references coded [0.29% Coverage]

Reference 1 - 0.05% Coverage

he likes it a lot, together everything he wins, I said

Reference 2 - 0.05% Coverage

group games that we play together with different foods are very

Reference 3 - 0.05% Coverage

we were doing the activities together, some days participation was very

Reference 4 - 0.05% Coverage

discussions, activities that we did together outside of the activities in

Nodes

✦	Name
[-]	A. The concept of mental stimulation and mental stimulating activities (Carer)
	1. The importance of mental stimulation
	2. Types of mental stimulation activities
	3. The importance of the carers' role in participating in mental stimulation activities
[-]	B. Taking part in iCST (Carer)
	1. Experience of taking part in iCST
	2. Specific activities
	3. Interesting and enjoyable activities
	4. Taking part or using iCST in the future
[-]	C. Potential benefits of taking part in iCST (Carer)
	1. Influence in everyday life
	2. Influence on the caregiving relationship
	3. Influence on cognitive function
	4. Influence on health and well-being
	5. Communication
[-]	D. Factors hindering taking part in iCST
	1. Specific factors helping PwD and carers to succeed in the use of iCST
[-]	E. Feasibility. Has iCST worked well for the PwD and the carer
[-]	F. iCST Materials (Carer)
	1. iCST Manual
	2. iCST Activity workbook
	3. iCST Toolkits
[-]	G. iCST training support (Carer)
	1. Overall support
	2. Set-up visit
	3. Telephone support
	4. Monitoring visit

Nodes

✦	Name
-	A. The concept of mental stimulation
-	1. Effects of mentally stimulation
	Participating in mental stimulation activities
	2. Types of mental stimulation activities
-	B. Experiencing of changes in everyday life as taking part in iCST
	1 Opportunity for mental stimulation
	2 Opportunity to communicate
	3 Enjoyment and pleasant activities
	4 Being active in everyday life
-	5 Brought the carer and the person with dementia together
	Carer awareness of the needs of the person with dementia
-	C. Carer adherence to the intervention
	Barriers to implementing the intervention
	Factors increasing intervention adherence

Coding Summary By Node

iCST Qualitative interviews (PwD)

10/11/2013 00:09

Aggregate	Classification	Coverage	Number Of Coding References	Reference Number	Coded By Initials	Modified On
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Node

Nodes\\A. The concept of mental stimulation and mentally stimulating activities

Document

Internals\\BEH Interview 1

Yes 0.0058 5

1 B 08/11/2013 18:30

find music actually stimulates

2 B 08/11/2013 18:31

I enjoyed what I did

3 B 08/11/2013 18:31

I think it is critically important

4 B 08/11/2013 18:32

you are talking about the course that went through

5 B 08/11/2013 18:32

couldn't believe how useful the whole thing is.

Internals\\BEH Interview 10

Yes 0.0210 12

1 B 08/11/2013 20:54

Definitely (taking part in mentally stimulating activities is important for people with memory problems)

2 B 08/11/2013 20:56

It gives an opportunity to think, reflect, review words and understand them, to reflect on what you want to say and what you're hearing somebody else saying and about the whole situation,

3 B 08/11/2013 20:56

it gives an opportunity to move into a situation, find the words, the phrases, the situations etc because living in a small situation as we are, there is not a great deal of opportunity for conversation really

Aggregate	Classification	Coverage	Number Of Coding References	Reference Number	Coded By Initials	Modified On
				4	B	08/11/2013 20:56
	Attending meetings is very stimulating					
				5	B	08/11/2013 20:57
	vocabulary, new ideas as well as like old ones					
				6	B	08/11/2013 20:58
	prayers.					
				7	B	08/11/2013 20:58
	some poems					
				8	B	08/11/2013 20:58
	attend a service in church is stimulating					
				9	B	08/11/2013 21:00
	That brings life to me.(Talking and companions)					
				10	B	08/11/2013 21:01
	Extremely, she's been absolutely wonderful					
				11	B	08/11/2013 21:01
	(the carer) has reminded me, brought me to the table, gone through things with me, helped me, had patience with me					
				12	B	08/11/2013 21:04
	she has been one who always supported me in every situation I've been in.					

Internals\\BEH Interview 2

Yes 0.0014 2

				1	B	08/11/2013 19:29
	Yes I enjoy it. (Singing)					
				2	B	08/11/2013 19:30
	I wouldn't like to be without him.					

Internals\\BEH Interview 6

Yes 0.0380 14

				1	B	08/11/2013 22:34
	If you don't lose use it you lose it					